

る。27人の小児がんの子どもを対象とした調査では57%が突出痛を24時間以内に経験しており、なかでも若年層(7~12歳)のほうがより多かった¹¹⁾。突出痛への対策をあらかじめとっておくことは、痛みの増強に対する不安を和らげるためには不可欠である。内服薬の場合には頓用(レスキュー)として1日量の1/6量の速効性製剤を服用し、持続注射であれば1~2時間分を早送りするという方法が一般的に行われている。

VI. 小児がんの子どもによくみられる痛み

1. 骨転移痛

がん細胞の骨髄での増殖や骨皮質への浸潤による痛みである。成人ではオピオイドとNSAIDsの併用が基本であり、必要に応じてパミドロン酸二ナトリウム(アレディア®)などのビスホスホネート製剤も用いられる。また病状によっては緩和的放射線治療や神経ブロックも行われる。最近になって放射性医薬品である塩化ストロンチウム(⁹⁰Sr)注射液が認可されたが、子どもに対する治療経験は少なく有用性は不明である。体動時に痛みが増強することが多いため、レスキューを体を動かす前に使うなどの工夫によってもある程度の痛みの緩和が可能である。

2. 神経障害性疼痛

小児がんで神経障害性疼痛の原因となるのは、がんによる脊髄や末梢神経の圧迫と抗癌剤の副作用としての末梢神経障害である。治療は成人で得られている知見を参考に、オピオイドと鎮痛補助薬の併用が行われることが多い。鎮痛補助薬としては、三環系抗うつ薬、コルチコステロイドなどが用いられる。ただし神経障害性疼痛は難治性であることが多く、効果と副作用のバランスをどの辺りで保つかを相談しながら

進めていかざるを得ないこともある。

3. 処置時の痛み

小児がんの治療中には、骨髄穿刺や腰椎穿刺などの強い痛みを伴う処置が多く、これらの痛みを上手にコントロールすることが子どものQOLを保つためには不可欠である。鎮痛薬としてはフェンタニルやケタミン(ケタラール®)が使用される。同時に抗不安作用と鎮静作用をもつミダゾラム(ドルミカム®)を併用することが多い。

おわりに

小児がんの子どもたちの痛みは、残念ながら十分にコントロールできていないのが現状と思われる。その原因は種々あるが、治療を担当している小児科医が多忙な日常診療の中で、子どもの症状コントロールを行わざるを得ない状態をまず改善しなくてはならないだろう。

今、小児がんと闘っている子どもたちに当面われわれができることは、近年急速に充実しつつある成人の緩和ケアチームとの連携を強めることである。将来的には、地域ごとにすべての子どもたちに適切な緩和ケアを提供できる体制を構築することを目指したい。

文 献

- 1) 恒松由記子, 佐々木祥子: 小児がん. 小児看護 8: 59-68, 2003
- 2) Wolfe J et al: Symptoms and suffering at the end of life in children with cancer. N Engl J Med 342: 326-333, 2000
- 3) Miser A et al: The prevalence of pain in a pediatric and young adult cancer population. Pain 29: 73-83, 1987
- 4) Ljungman G et al: Pain in paediatric oncology: Interviews with children, adolescents and their parents. Acta Paediatr 88: 623-630, 1999
- 5) World Health Organization: Cancer Pain Relief and Palliative Care in Children. Geneva, 1998

Psychological and behavioral mechanisms influencing the use of complementary and alternative medicine (CAM) in cancer patients

K. Hirai^{1*}, K. Komura², A. Tokoro³, T. Kuromaru⁴, A. Ohshima⁵, T. Ito⁶, Y. Sumiyoshi⁷ & I. Hyodo⁸

¹Department of Psychology and Behavioral Sciences, Graduate School of Human Sciences, Center for the Study of Communication Design, and Department of Complementary and Alternative Medicine, Graduate School of Medicine; ²Graduate School of Human Sciences, Osaka University, Osaka; ³Department of Psychosomatic Medicine, National Hospital Organization, Kinki-chuo Chest Medical Center, Osaka; ⁴Department of Palliative Care, Hikone Hospital, Hikone; ⁵Department of Psycho-Oncology, National Kyushu Cancer Center, Kyushu; ⁶Department of Complementary and Alternative Medicine, Graduate School of Medicine, Osaka University, Osaka; ⁷Department of Urology, Shikoku Cancer Center, Matsuyama; ⁸Division of Gastroenterology, University of Tsukuba, Tsukuba, Ibaraki, Japan

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Background: This study explored the psychological and behavioral mechanisms of complementary and alternative medicine (CAM) use in Japanese cancer patients using two applied behavioral models, the transtheoretical model (TTM), and theory of planned behavior (TPB).

Patients and methods: Questionnaires were distributed to 1100 patients at three cancer treatment facilities in Japan and data on 521 cancer patients were used in the final analysis. The questionnaire included items based on TTM and TPB variables, as well as three psychological batteries.

Results: According to the TTM, 88 patients (17%) were in precontemplation, 226 (43%) in contemplation, 33 (6%) in preparation, 71 (14%) in action, and 103 (20%) in maintenance. The model derived from structural equation modeling revealed that the stage of CAM use was significantly affected by the pros, cons, expectation from family, norms of medical staff, use of chemotherapy, period from diagnosis, and place of treatment. The primary factor for the stage of CAM use was the expectation from family.

Conclusions: The findings revealed the existence of a number of psychologically induced potential CAM users, and psychological variables including positive attitude for CAM use and perceived family expectation greatly influence CAM use in cancer patients.

Key words: CAM, cancer patients, psychological adjustment, theory of planned behavior, transtheoretical model

introduction

Cancer patients use nutritional supplements, psychological techniques, and natural medical approaches together with conventional medicine, or in replace of conventional therapy, which are so-called complementary and alternative medicine (CAM). Recent surveys have demonstrated the high prevalence of CAM use by cancer patients. Sixty-seven percent of Canadian respondents reported using CAM, most often in an attempt to boost the immune system [1]. The first national survey on the use of CAM in Japan revealed that 45% of Japanese cancer patients have used CAM [2].

CAM is defined by the National Center for Complementary and Alternative Medicine as 'a group of diverse medical and health care systems, practices, and products that are not presently considered to be part of conventional medicine' [3]. In addition, a new operational definition of CAM was proposed

that it should include patients' perspectives, such as individual goals, objectives, and beliefs of the patients [4]. Therefore, it is important to consider psychological aspects such as patients' background, reasons or intentions for using CAM in oncology.

Several studies have explored the background and reasoning behind CAM use [1, 5–7]. CAM use in early-stage breast cancer patients was regarded as a marker of greater psychosocial distress and a worse quality of life [7] and advanced-stage cancer patients who used CAM had higher levels of anxiety and pain, lower satisfaction with conventional medicine, and a lower need for control over treatment decisions [8]. Alternatively, the use of CAM by cancer patients has not been associated with perceived distress or poor compliance with medical treatment [9]. However, the psychological and behavioral mechanisms of CAM use have not yet been clarified. Therefore, we carried out a multicenter cross-sectional survey to explore the psychological mechanism of CAM use in Japanese cancer patients from patients' perspectives, using the transtheoretical model (TTM), and the theory of planned behavior (TPB).

*Correspondence to: Dr K. Hirai, Graduate School of Human Sciences, Osaka University, 1-2 Yamadaoka, Suita Osaka 565-0871, Japan.
Tel: +81-6-6879-8060; Fax: +81-6-6879-8060; E-mail: khirai@grappo.jp

The TTM [10] is useful for explaining changes in health behavior and has been used in various programs such as smoking cessation [11], genetic testing for colorectal cancer [12], and mammography adoption [13]. In the TTM, the decisional balance between pros and cons—positive and negative attitudes for the behavior—will account for the state of change observed during five stages: precontemplation, contemplation, preparation, action, and maintenance [10]. We adopted this classification to explain the behavioral intention of patients using CAM in cancer treatment. Moreover, self-efficacy, which acts as a mediating function for the psychological adjustment of cancer patients [14, 15], is an important factor affecting a person's movement from one stage to another.

The TPB [16] examines behavioral intentions based on three major components: the patient's attitude towards the behavior, perceived control, and subjective norms. In cases of cancer patients, attitude towards behavior may include perceived effectiveness of treatment, anxiety regarding side-effects, etc. Perceived control is the individual's perception of the extent to which performance of the behavior is easy or difficult, and is synonymous with the concept of self-efficacy [16]. Subjective norms in cancer CAM include expectation from family members, and norms of medical staff towards the patients.

Our hypotheses are as follows: (i) cancer patients are classified into five stages of CAM use, (ii) the stage of CAM use is explained by TTM and TPB variables, and (iii) perceived control positively correlates with CAM use and mediates between CAM use and psychological adjustment.

patients and methods

participants

This study was approved by the institutional review boards of the Kinki Chuo Chest Disease Center, National Kyushu Cancer Center, and National Shikoku Cancer Center. From April 2005 to August 2005, a total of 1100 questionnaires were distributed to patients at each institute. Patients were enrolled in the study after their attending physician assessed if they met the following conditions: were receiving medical treatment through the outpatient or inpatient units at any of the three cancer centers, had an Eastern Cooperative Oncology Group performance status [17] from zero to three, were physically able to fill in the questionnaires by themselves, and had no cognitive impairment. On the questionnaire, we explained the purpose of the study and the fact that returning the questionnaire would be regarded as consent for participation; though we asked the patients to return the questionnaires anonymously.

measures

For this study, we developed our own questionnaire to examine CAM use in cancer patients (available from the authors). The questionnaire contained 85 items and it took about 20 min to complete. On the cover page of the questionnaire, CAM was defined using same definition of our previous survey [2]: 'as any therapy is not included in the orthodox biomedical framework of care for patients, which includes remedies used without the approval of the relevant government authorities of new drugs after peer review of preclinical experiments and clinical trials regulated by law. Health insurance does not usually cover the cost of CAM, and patients are generally liable for all expenses incurred by CAM use. CAM may include use of natural products from mushrooms, herbs, green tea, shark cartilage, megavitamins, or other special foods, and may

incorporate acupuncture, aromatherapy, massage, meditation, etc'. Additionally, a sheet containing 20 examples of CAM therapies and products was attached to the questionnaire. The first portion of the questionnaire asked for information on the patients' background, including type of disease, age at onset, current age, gender, educational level, economic status, type of cancer treatment, satisfaction with treatment, smoking, drinking, and social support measured by the single item Tangible Social Support Scale [18].

The second part of the questionnaire included items originally designed to evaluate the cancer CAM-specific TTM and TPB variables. To measure the patients' subjective intention with regard to CAM use, we additionally defined cancer CAM use as those 'using any supplements or dietary foods or receiving any therapy that appears to have anticancer effects or auxiliary effect to that of conventional cancer therapy'. Respondents were asked to rate themselves based on the five stages of the TTM [10]: precontemplation ('I have no interest in using CAM'), contemplation ('I have been thinking that I might want to use CAM'), preparation ('I am preparing to use CAM'), action ('I have already used CAM in the last 6 months'), and maintenance ('I have already used CAM for >6 months'). The next section was composed of 27 items measuring TTM and TPB variables. The items were measured on a five-point Likert-type scale that ranged from 'not at all' (1) to 'extremely' (5). They included following five categories, (i) positive attitudes for CAM; (ii) pros; (iii) cons; (iv) expectation from family; and (v) norms of medical staff. The items were developed in our previous study on CAM [2] and another study on dietary food intake [19]. We used 16 from 27 items using confirmatory factor analysis on the current data as structurally valid and reliable items (Table 1). Also, content validity of the all TTM and TPB items in this part was confirmed by experts of two physicians, one psychiatrist and two psychologists.

To assess psychological adjustment, we used the Japanese version [20] of the Hospital Anxiety and Depression Scale (HADS) [21], which has 14 questions on anxiety and depression with each question rated from 0 to 3. The validity and reliability of the Japanese HADS in cancer patients has been confirmed previously [22].

To assess perceived control in patients, we used the Self-Efficacy for Advanced Cancer (SEAC) scale, which was designed to evaluate self-efficacy of cancer patients [23]. The SEAC scale has 18 items with three subscales: symptom coping efficacy, activities of daily living efficacy (ADE), and affect regulation efficacy (ARE). The scale was formatted on an 11-point Likert-type scale ranging from 0 (not at all confident) to 100 (totally confident). The reliability and validity of this scale were also confirmed [23].

Finally, the Japanese version of the MD Anderson Symptom Inventory (MDASI-J) [24] was developed as a brief multiple-symptom assessment scale. It consisted of 13 symptom items [25], and its validity and reliability were confirmed [24]. We used 10 of the 13 physical symptom items for our statistical analyses since the items for distress, sadness, and remembrance were significantly and highly correlated with the HADS total score ($r = 0.0479$, $P < 0.001$; $r = 0.456$, $P < 0.001$; $r = 0.334$, $P < 0.001$, respectively).

statistical analyses

Descriptive analyses were carried out summarizing the participants' backgrounds and scores following psychological measurements. Those with >30% missing values on the questionnaire were excluded from the analyses. The factors predicting stage of CAM use were analyzed through univariate analysis using the analysis of variance. In order to carry out multivariate analyses, we transformed the participants' responses for the stage of CAM use into a numeric scale ranging from 1 to 5 points (1, precontemplation; 2, contemplation; 3, preparation; 4, action; and 5, maintenance), according to a previous study [15]. Next, structural equation modeling (SEM) using the maximum likelihood method was carried out to

Table 1. Items measuring TTM and TPB variables and factor definitions

Items	Factor loadings
Positive attitudes for CAM (Cronbach alpha = 0.83)	
Definition: The items represented the high-perceived availability and importance of CAM use for the patients.	
1. CAM is important to retain physical strength.	0.80
2. Hospital care alone is not enough.	0.68
3. Convenience is an important determinant of starting to use CAM.	0.84
4. The cost of CAM is important.	0.66
Pros (Cronbach alpha = 0.90)	
Definition: The items represented patients' perceived positive outcomes of CAM use.	
5. The use of CAM leads to the cure of disease.	0.90
6. The use of CAM halts the progression of disease.	0.89
7. The use of CAM boosts physical and immune strength.	0.90
8. CAM has fewer side-effects compared with medical care.	0.69
Cons (Cronbach alpha = 0.70)	
Definition: The items represented patients' perceived negative outcomes of CAM use.	
9. The use of CAM has bad influence on medical care.	0.79
10. The use of CAM deteriorates disease.	0.89
11. I am aware of the side-effects of CAM.	0.53
12. I am aware of the dependence liability of CAM.	0.53
Expectation from family (Cronbach alpha = 0.65)	
Definition: The items represented patients' perceived expectations and recommendations from family.	
13. My family/friends believe that I should be actively engaged in the use of CAM.	0.74
14. My use of CAM is influenced by the opinions of my family/friends.	0.65
Norms of medical staff (Cronbach alpha = 0.34)	
Definition: The items represented patients' perceived expectation, recommendation from patients' medical staff, or their norms.	
15. My doctors/nurses believe that I should be actively engaged in the use of CAM.	0.68
16. My use of CAM is influenced by the opinions of my doctors/nurses.	0.30

Fit indices from the confirmatory factor analysis for items and factors indicated above: chi-square (96) = 345.5; $P = 0.001$; GFI = 0.92; AGFI = 0.88; CFI = 0.94; RMSEA = 0.07. TTM, transtheoretical model; TPB, theory of planned behaviour; CAM, complementary and alternative medicine.

test the model. Because the model needed a parsimonious structure, we used the mean scores of SEAC as 'self-efficacy', the total score of HADS as 'psychological distress', and the mean scores of 10 items of MDASI-J as 'physical symptom'. We conducted all statistical analyses using SPSS (version 14.0) and AMOS (version 5.0.1) software packages.

results

response rate to questionnaire

Of the 1100 questionnaires, 750 were given to inpatients and 350 to outpatients. Out of the 651 questionnaires returned

(response rate 59.2%), 521 were valid for statistical analyses. The rest ($n = 130$) were invalid because of the lack of major information such as disease name or stage of CAM use. Moreover, questionnaires from noncancer patients were excluded from the analyses. Thus, the rate of valid replies was 47.4%.

backgrounds of patients and distribution of CAM use

The participants consisted of 246 males and 270 females, and five unknowns. Table 2 summarizes the demographic and diagnostic information of the participants. For staging, 88 patients (16.9%) were in precontemplation, 226 (43.4%) in contemplation, and 31 (6.6%) in preparation among the 347 CAM nonusers (66.6%), with 71 (13.6%) in action and 103 (19.8%) in maintenance among the 174 CAM users (33.4%). Table 1 also shows the prevalence of the five stages of CAM use categorized by demographic and medical status variables. The prevalence of CAM use in the higher stages, including action and maintenance, was significantly higher in patients who received chemotherapy ($P < 0.001$), those dissatisfied with current conventional treatment ($P < 0.05$), and outpatients ($P < 0.001$).

psychosocial factors associated with the stages of CAM use

Table 3 shows the mean response and the results of the univariate analyses for psychological variables, physical symptom variables, and social support obtained from patients at each of the five stages of CAM use. There were significant differences amongst patients in the five stages based on pros ($P < 0.001$), cons ($P < 0.001$), positive attitude for CAM ($P < 0.001$), and expectation from family members ($P < 0.001$). There was a slightly higher response on ADE ($P < 0.10$) in patients who were in the action and maintenance stages.

structural model for stages of CAM use

We carried out SEM by first selecting 14 variables in the initial model because they were observed to be significant predictors in the univariate analysis or were essential components for the TTM and TPB theories: use of chemotherapy, period from diagnosis, whether need for treatment was met, treatment place, stage of CAM use, psychological distress, pros, cons, positive attitude, expectation from family members, norms of medical staff, self-efficacy, psychological distress, physical symptoms, and social support. Next, we drew all paths according to the results of the correlation analysis. Since there was a significantly strong correlation between the pros and a positive attitude ($r = 0.80$, $P < 0.001$), and since the explanation by the TTM is given a priority for our purposes, we dropped positive attitude from the initial model. We repeated the SEM and sequentially dropped paths that were not significant until all the paths in the model became significant ($P < 0.05$). The variable 'met need for treatment' was dropped from the model because all the paths from this variable became not significant.

Figure 1 represents the final model. The fit indices for this model were excellent and included the following: chi-square

Table 2. Patients' background and CAM use stage

	Total	Precontemplation		Contemplation		Preparation		Action		Maintenance		P (χ ² test)
	n	n	%	n	%	n	%	n	%	n	%	
Total	521	88	16.9	226	43.4	33	6.3	71	13.6	103	19.8	
Age years												
>60	262	47	17.9	120	45.8	13	5.0	31	11.8	51	19.5	0.446
≤60	253	40	15.8	105	41.5	19	7.5	40	15.8	49	19.4	
Gender												
Male	270	43	15.9	112	41.5	22	8.1	35	13.0	58	21.5	0.336
Female	246	45	18.3	110	44.7	11	4.5	36	14.6	44	17.9	
Education												
High school	318	50	15.7	141	44.3	7.2	7.2	46	14.5	58	18.2	0.561
Posthigh school	174	34	19.5	67	38.5	10	5.7	25	14.4	38	18.2	
Period from diagnosis												
≤1 year	261	56	21.5	118	45.2	20	7.7	46	17.6	21	8.0	0.000
>1 year	246	29	11.8	102	41.5	10	4.1	25	10.2	80	32.5	
Conventional treatment												
Chemotherapy	393	58	14.8	158	40.2	28	7.1	61	15.5	88	22.4	0.001
Nonchemotherapy	122	27	22.1	66	54.1	5	4.1	10	8.2	14	11.5	
Treatment met patient's needs												
Yes	371	72	19.4	161	43.4	18	4.9	49	13.2	71	19.1	0.045
No	150	16	10.7	65	43.3	15	10.0	22	14.7	32	21.3	
House income												
≥U7 000 000	113	17	15.0	48	42.5	5	4.4	13	11.5	30	26.5	0.438
<U7 000 000	334	53	15.9	144	43.1	23	6.9	50	15.0	64	19.2	
Treatment place												
Inpatient ward	360	67	18.6	167	46.4	27	7.5	53	14.7	46	12.8	0.000
Palliative care unit	24	2	8.3	8	33.3	5	20.8	3	12.5	6	25.0	
Outpatient clinic	161	21	13.0	59	36.6	6	3.7	18	11.2	57	35.4	
Cancer												
Lung	190	28	14.7	69	36.3	11	5.8	34	17.9	48	25.3	0.137
Breast	55	11	20.0	30	54.5	4	7.3	4	7.3	6	10.9	
Gastrointestinal	79	13	16.5	40	50.6	6	7.6	10	12.7	10	12.7	
Gynecological	61	8	13.1	28	45.9	2	3.3	7	11.5	16	26.2	
Other	121	24	19.8	54	44.6	9	7.4	13	10.7	21	17.4	

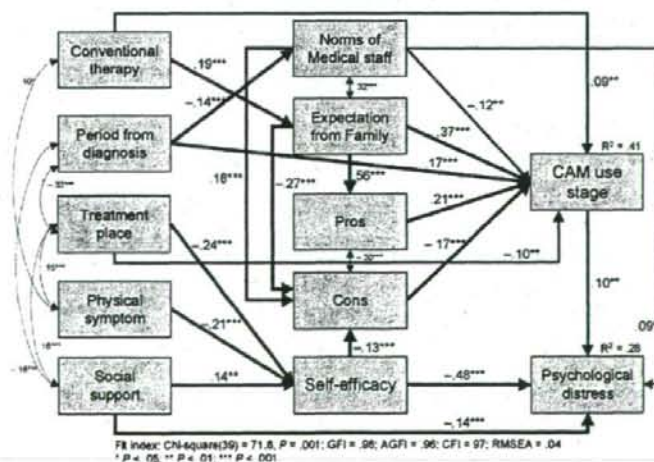


Figure 1. Structural model for the stage of CAM use and psychological adjustment.

Table 3. Descriptive data and ANOVA: mean comparison among CAM use stages

Measure	Precontemplation		Contemplation		Preparation		Action		Maintenance		P (F test)
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
TTM components*											
Pros	20.74	1.09	20.28	0.84	0.52	0.64	0.67	0.86	0.52	0.79	0.000
Cons	0.31	0.93	0.30	0.90	0.17	0.91	20.58	0.83	20.52	1.03	0.000
TPB components*											
Positive attitude	20.84	0.99	20.27	0.90	0.58	0.62	0.61	0.77	0.59	0.73	0.000
Expectation from family member	20.71	0.81	20.35	0.80	0.58	0.85	0.63	0.93	0.64	0.88	0.000
Norms of medical staff	20.10	1.06	0.05	0.92	0.08	1.11	0.12	0.95	20.14	1.09	0.335
Self-efficacy											
ARE	60.34	26.28	57.93	23.33	57.72	23.51	64.82	20.34	61.17	19.83	0.241
SCE	54.80	28.38	53.61	23.16	54.48	26.21	61.21	20.97	57.92	21.98	0.167
ADE	66.33	27.48	64.83	25.44	67.26	25.47	72.85	19.00	70.89	23.75	0.097
Total	60.49	26.44	58.79	23.18	59.82	23.87	66.30	19.01	63.33	20.68	0.139
HADS											
Anxiety	5.58	3.65	5.71	3.86	6.02	4.11	5.58	4.31	6.14	3.90	0.335
Depression	5.42	3.29	5.83	3.39	6.13	3.82	5.66	4.11	6.48	4.04	0.841
Total	11.00	6.26	11.54	6.66	12.15	7.30	11.24	8.05	12.62	7.26	0.533
Physical symptom											
Pain	29.01	33.68	28.13	31.88	37.42	32.66	32.50	34.09	23.70	30.61	0.227
Lack of appetite	33.61	34.56	27.41	30.30	31.43	29.15	32.35	32.97	24.00	30.48	0.219
Disturbed sleep	33.73	33.52	27.63	27.72	29.03	24.81	34.06	29.42	32.60	32.27	0.335
Nausea	20.95	32.51	22.57	30.67	18.71	27.78	22.65	32.07	20.10	32.28	0.937
Fatigue	38.10	29.76	32.80	27.59	37.74	28.37	34.06	30.06	37.92	29.71	0.461
Dyspnea	23.37	29.81	18.62	26.40	19.67	19.91	21.32	27.64	26.02	29.17	0.235
Numbness or tingling	28.80	32.25	25.79	29.21	27.33	30.16	28.26	31.85	30.30	33.53	0.800
Drowsy	34.88	26.86	28.69	26.86	37.00	26.67	31.76	26.26	35.54	27.62	0.140
Vomiting	20.85	32.93	18.97	30.53	16.00	28.96	20.00	30.71	20.70	31.92	0.944
Dry mouth	30.49	31.70	27.16	28.82	31.67	30.41	24.93	27.15	28.63	28.91	0.725
Physical symptom ^b	29.59	22.87	25.90	21.62	28.73	18.17	28.38	21.80	28.10	22.53	0.695
Social support											
Tangible assistance	6.09	5.27	5.57	4.37	6.71	4.90	6.12	3.85	5.12	2.88	0.307

*Z score.

^bAverage score among 10 physical symptom variables.

ANOVA, analysis of variance; CAM, complementary and alternative medicine; SD, standard deviation; TTM, transtheoretical model; TPB, theory of planned behaviour; ARE, affect regulation efficacy; SCE, symptom coping efficacy; ADE, activity of daily living efficacy; HADS, Hospital Anxiety and Depression Scale.

(39) = 71.8, $P = 0.001$; Goodness of fit index = 0.98; Adjusted goodness of fit index = 0.96; Comparative Fit Index = 0.97; and Root Mean Square Error of Approximation = 0.04.

Overall, the final model accounted for 41% of the variance in the stage of CAM use and 28% of the variance in psychological distress. The parameter with the highest value that explained the stage of CAM use was expectation from family members ($\beta = 0.37$, $P < 0.001$). Furthermore, norms of medical staff and pros and cons all had significant direct effects on the stage of CAM use ($\beta = -0.12$, $P < 0.01$; $\beta = 0.21$, $P < 0.001$; and $\beta = 20.17$, $P < 0.001$, respectively). The demographic and medical status variables that significantly explained the stage of CAM use included receiving chemotherapy ($\beta = 0.09$, $P < 0.01$), period from diagnosis ($\beta = 0.37$, $P < 0.001$), and treatment place ($\beta = 20.10$, $P < 0.01$). The parameter with the highest value that explained psychological distress was self-efficacy ($\beta = 0.17$, $P < 0.001$). Moreover, social support significantly affected psychological distress ($\beta = 20.14$, $P < 0.001$).

Finally, the stage of CAM use significantly, though only partially, affected psychological distress ($\beta = 0.10$, $P < 0.01$).

discussion

Our survey revealed that 33% of the participants used CAM as a replacement or an adjuvant to conventional cancer treatment. The rate of CAM use in this study approximately corresponded to the rate in a previous study [26], but was lower than the rate observed in a Japanese national survey [2]. This is likely due to the fact that our sample consisted of a much smaller number of patients from the palliative care unit ($n = 24$, 4.7%) compared with the previous study ($n = 289$, 9.3%). When we grouped participants into the five TTM stages of CAM use, the contemplation stage had the largest population ($N = 226$, 43.4%). Although these participants did not use CAM, they expressed interest in using it in the near future. Therefore, we concluded that a majority of our participants were potential CAM users.

Using SEM, we determined that 41% of the variance in advance of the CAM use stage was mainly due to the following TTM and TPB variables: expectation from family (positive), pros (positive), norms of medical staff (negative), and cons (negative). Three demographic and medical status variables were statistically significant in explaining CAM use, but their size was smaller than the other psychological variables. Therefore, we concluded that psychological variables are important factors promoting CAM use. With psychological variables, the pattern in which pros were positive predictors and cons were negative predictors of a person's stage, is consistent with the theoretical postulation of the TTM [10]. The most frequent pro notion regarding CAM was that it 'boosts physical and immune strength', while the most frequent con was that it had 'unpleasant side-effects' ['agree' and 'strongly agree' response: N = 272 (53%); N = 187 (38%), respectively]. Thus, beliefs regarding the positive outcome of CAM were strong motivations for CAM use, but patients simultaneously worried about the adverse effects. Therefore, if the patients' perceived balance between the pros and cons of CAM was to be changed by acquiring new information on CAM—e.g. the positive effect of a certain CAM product was empirically proven by a clinical trial—many patients in the contemplation stage would likely then use CAM. Therefore, it is important to provide evidence based and easy to understand information on CAM use in a systematic way, such as guidebooks or web resources, and to develop clinical guidelines on CAM use.

Another unique feature of CAM use that we determined is that the expectation from family in TPB explained the largest part of the variance in the CAM use stage. Previous studies have reported that family and friends of cancer patients generally provided information, supported the decision, or recommended the use of CAM [2, 27, 28], and that CAM users were not autonomous problem solvers [29]. Therefore, our result makes much clear of the critical role that patient recognition of family pressure plays during the decision-making process for CAM use.

Previous studies have indicated that the use of CAM was a marker of bad psychological adjustment [6] and had positive effects on patients' sense of control [30]. On our results, progressed stage of CAM use significantly but not strongly predicted psychological distress, which was mainly explained by self-efficacy, that is, perceived control, and it did not directly explain CAM use stage and mediated by cons. In summary, CAM use did not directly provide perceived control to patients but a little worse psychological adjustment. We could not obtain the evidence that perceived control had strongly mediated the relationship between CAM use and psychological adjustment.

The limitations to this study include the cross-sectional design and sample. Use of SEM could have made clear of multiple relationships among variables in the cross-sectional design. This study also used a convenient sample recruited from three cancer centers. In order to obtain epidemiological details of the CAM use, we need to carry out a large sample prospective study confirming the results of this study. The response rate of our study, 59% was slightly higher than that of our previous national survey, 57% [2]. However, the valid

response rate was 47%, mainly due to the missing of a single item for stage of CAM use. These indicated that sampling was valid, however it will limit generality of our results. It might be needed to improve assessment for stage of CAM use in the questionnaire.

In conclusion, this study using two psychological model provided strong evidence that the existence of psychologically induced potential CAM users and psychological variables including positive attitude for CAM use and perceived family expectation greatly influence CAM use in cancer patients.

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references

- Boon H, Stewart M, Kennard MA et al. Use of complementary/alternative medicine by breast cancer survivors in Ontario: prevalence and perceptions. *J Clin Oncol* 2000; 18: 2515–2521.
- Hyodo I, Amano N, Eguchi K et al. Nationwide survey on complementary and alternative medicine in cancer patients in Japan. *J Clin Oncol* 2005; 23: 2645–2654.
- National Center for Complementary and Alternative Medicine. What is Complementary and Alternative Medicine (CAM)? <http://nccam.nih.gov/health/whatiscam/> (28 July 2007, date last accessed).
- Caspi O, Sechrest L, Pitluk HC et al. On the definition of complementary, alternative, and integrative medicine: societal mega-stereotypes vs. the patients' perspectives. *Altern Ther Health Med* 2003; 9: 58–62.
- Cassileth BR, Deng G. Complementary and alternative therapies for cancer. *Oncologist* 2004; 9: 80–89.
- Paltiel O, Avitzour M, Peretz T et al. Determinants of the use of complementary therapies by patients with cancer. *J Clin Oncol* 2001; 19: 2439–2448.
- Burstein HJ. Discussing complementary therapies with cancer patients: what should we be talking about? *J Clin Oncol* 2000; 18: 2501–2504.
- Correa-Velez I, Clavarino A, Barnett AG, Eastwood H. Use of complementary and alternative medicine and quality of life: changes at the end of life. *Palliat Med* 2003; 17: 695–703.
- Soliner W, Maislinger S, DeVries A et al. Use of complementary and alternative medicine by cancer patients is not associated with perceived distress or poor compliance with standard treatment but with active coping behavior: a survey. *Cancer* 2000; 89: 873–880.
- Prochaska JO, DiClemente CC. Stages and processes of self-change of smoking: toward an integrative model of change. *J Consult Clin Psychol* 1983; 51: 390–395.
- Prochaska JO, DiClemente CC. Self change processes, self efficacy and decisional balance across five stages of smoking cessation. *Prog Clin Biol Res* 1984; 156: 131–140.
- Menne S, Markowitz A, Winawer S et al. Correlates of colorectal cancer screening compliance and stage of adoption among siblings of individuals with early onset colorectal cancer. *Health Psychol* 2002; 21: 3–15.
- Lauver DR, Henriques JB, Settersten L, Bumann MC. Psychosocial variables, external barriers, and stage of mammography adoption. *Health Psychol* 2003; 22: 649–653.

14. Hirai K, Suzuki Y, Tsuneto S et al. A structural model of the relationships among self-efficacy, psychological adjustment, and physical condition in Japanese advanced cancer patients. *Psychooncology* 2002; 11: 221-229.
15. Honda K, Gorin SS. A model of stage of change to recommend colonoscopy among urban primary care physicians. *Health Psychol* 2006; 25: 65-73.
16. Ajzen I. The theory of planned behavior. *Organ Behav Hum Decis Process* 1991; 50: 179-211.
17. Le Chevalier T, Brisgand D, Douillard JY et al. Randomized study of vinorelbine and cisplatin versus vindesine and cisplatin versus vinorelbine alone in advanced non-small-cell lung cancer: results of a European multicenter trial including 612 patients. *J Clin Oncol* 1994; 12: 360-367.
18. Blake RL Jr, McKay DA. A single-item measure of social supports as a predictor of morbidity. *J Fam Pract* 1986; 22: 82-84.
19. Corner M, Kirk SF, Cade JE, Barrett JH. Why do women use dietary supplements? The use of the theory of planned behaviour to explore beliefs about their use. *Soc Sci Med* 2001; 52: 621-633.
20. Kitamura T. The hospital anxiety and depression scale [in Japanese]. *Arch Psychiatr Diagn Clin Eval* 1993; 4: 371-372.
21. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand* 1983; 67: 361-370.
22. Kugaya A, Akechi T, Okuyama T et al. Screening for psychological distress in Japanese cancer patients. *Jpn J Clin Oncol* 1998; 28: 333-338.
23. Hirai K, Suzuki Y, Tsuneto S et al. Self-efficacy scale for terminal cancer [in Japanese]. *Jpn J Psychosom Med* 2001; 41: 19-27.
24. Okuyama T, Wang XS, Akechi T et al. Japanese version of the MD Anderson Symptom Inventory: a validation study. *J Pain Symptom Manage* 2003; 26: 1093-1104.
25. Cleeland CS, Mendoza TR, Wang XS et al. Assessing symptom distress in cancer patients: the M.D. Anderson Symptom Inventory. *Cancer* 2000; 89: 1634-1646.
26. Eguchi K, Hyodo I, Saeki H. Current status of cancer patients' perception of alternative medicine in Japan. A preliminary cross-sectional survey. *Support Care Cancer* 2000; 8: 28-32.
27. Boon H, Brown JB, Gavin A et al. Breast cancer survivors' perceptions of complementary/alternative medicine (CAM): making the decision to use or not to use. *Qual Health Res* 1999; 9: 639-653.
28. Molesiotis A, Scott JA, Kearney N et al. Complementary and alternative medicine use in breast cancer patients in Europe. *Support Care Cancer* 2006; 14: 260-267.
29. Boon H, Westlake K, Deber R, Moineddin R. Problem-solving and decision-making preferences: no difference between complementary and alternative medicine users and non-users. *Complement Ther Med* 2005; 13: 213-216.
30. Sparber A, Bauer L, Curt G et al. Use of complementary medicine by adult patients participating in cancer clinical trials. *Oncol Nurs Forum* 2000; 27: 623-630.

Discrimination between worry and anxiety among cancer patients: development of a brief cancer-related worry inventory

Kei Hirai^{1,2,*}, Mariko Shiozaki³, Hiroko Motooka⁴, Hirokazu Arai⁵, Atsuko Koyama⁶, Hiroki Inui⁷ and Yosuke Uchitomi⁸

¹Center for the Study of Communication Design, Department of Psychology and Behavioral Sciences, Graduate School of Human Sciences, Japan

²Department of Complementary and Alternative Medicine, Graduate School of Medicine, Osaka University, Osaka, Japan

³The Japan Society for the Promotion of Science, Japan

⁴Graduate Schools of Clinical Psychology, Kansai University of Welfare Sciences, Japan

⁵Department of Health Psychology, Osaka University of Human Sciences, Japan

⁶Department of Psychosomatic Medicine, Kinki University School of Medicine, Japan

⁷Department of Surgery, Kinki University School of Medicine, Japan

⁸Research Center for Innovative Oncology, National Cancer Center Hospital East, Japan

*Correspondence to:
Graduate School of Human
Sciences, Osaka University,
1-2 Yamadaoka, Suita,
Osaka 565-0871, Japan.
E-mail: khirai@grappo.jp

Abstract

Objectives: A psychometric scale for assessing cancer-related worry among cancer patients, called the Brief Cancer-Related Worry Inventory (BCWI), was developed.

Methods: A cross-sectional questionnaire survey for item development was conducted of 112 Japanese patients diagnosed with breast cancer, and test-retest validation analysis was conducted using the data from another prospective study of 20 lung cancer patients. The questionnaire contained 15 newly developed items for cancer-related worry, the Hospital Anxiety and Depression Scale, The Impact of Event Scale Revised, and the Medical Outcomes Study Short Form-8.

Results: Exploratory factor analysis of the 15 items yielded a 3-factor structure including (1) future prospects, (2) physical and symptomatic problems and (3) social and interpersonal problems. A second-order confirmatory factor analysis identified a second-order factor called cancer-related worry and confirmed the factor structure with an acceptable fit (chi-square (df = 87) = 160.16, $P = 0.001$; GFI = 0.83; CFI = 0.92; RMSEA = 0.09). The internal consistency and test-retest reliability were confirmed with the lung cancer sample. Multidimensional scaling found that cancer-related worry is separate from anxiety, depression, and posttraumatic stress disorder (PTSD) symptoms.

Conclusion: Our study succeeded in developing and confirming the validity and reliability of a BCWI. The study also confirmed the discriminable aspects of cancer-related worry from anxiety, depression, and PTSD symptoms.

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Introduction

Being diagnosed with cancer is itself a major stressful event for cancer patients, and they subsequently experience other kinds of stressful events related to cancer and its treatment. As the first reaction to these negative events and cancer-related experiences, a number of cancer patients experience feelings of anxiety, and anxiety sometimes becomes a clinically important problem in its own right [1].

Anxiety in cancer patients is a concept for negative state of mind and has been defined as intrusive and unpleasant anxious thoughts; often

involving recurrence of disease, death, or disability; and causing considerable disruption in concentration, decision-making, sleep, and social functioning [1]. Several anxiety-related measurement scales have been frequently used to assess anxiety-related moods or emotions of cancer patients. They include the State-Trait Anxiety Inventory and the Hospital Anxiety and Depression Scale (HADS). These scales mainly measure the patient's somatic symptoms caused by autonomic nervous activities, which correspond to a patient's level of anxiety, but do not evaluate what the patient is anxious or worried about. Therefore, the contents and types of causes, that is, the stressors that evoke anxiety have

not been clarified. In addition, there is a clinical need to evaluate the contents of patients' anxious status with convenient means to detect patients' needs or preferences in order to design individualized care for the patients.

For that purpose, several studies to evaluate stressors that would make the patients anxious have been undertaken in order to define unmet needs or concerns. The studies of unmet needs for cancer patients addressed psychological factors such as fear, anxiety, information about the medical system, physical factors, activity of daily living, disease itself, side effects of treatment, human relations, social support, social issues, and sexual issues [2-5]. The studies revealed types and contents of concerns of cancer patients. Domains of general concerns for cancer patients were cancer itself, disability, family, work, economic status, loss of independence, physical distress, psychological distress, medical uncertainty, and death [6-12].

The term worry has been used as a cardinal symptom in general anxiety disorder in *Diagnostic and Statistical Manual of Mental Disorders-Revised* (DSM-III-R) [13]. According to Wells' metacognitive theory, worry is a chain of catastrophic thoughts that are predominantly verbal, consists of the contemplation of potentially dangerous situations and of personal coping strategies and can become the focus of an individual's concern [14]. Therefore, worry is a predominantly cognitive activity, [15] which is characterized by negative thought and images about the outcome of events, particularly concerns about the future, and a part of anxiety but discriminable from it. In the cancer literature, worry indicates the fear of having cancer; several studies of cancer worry were investigated for cancer screening settings [16,17] such as mammography [18], ovarian cancer [19], and prostate cancer screening [20]. There are few studies concerning worry in cancer patients after their diagnosis. It was reported that the level of prediagnostic intrusive thoughts would provide a significant, useful, and practical method for clinicians to identify in advance those patients likely to worry excessively following a diagnosis of cancer [21]. A worry content scale was developed to assess multiple dimensions of worry in cancer patients [22].

However, the conceptual difference between worry and anxiety is unclear, especially from empirical perspectives, and it is necessary to confirm the validity of discrimination between the measures for worry and for anxiety. Therefore, we performed a cross-sectional study of breast cancer patients and a prospective observational study of lung cancer patients with the following aims: (1) to develop a scale to assess the variation in contents and strength of cancer-related worry thoughts; (2) to confirm the validity and reliability of the scale;

and (3) to test discrimination between cancer-related worry and anxiety.

Methods

Participants

This study involved consecutive sampling and was composed of two different samples, which were breast cancer patients after surgery for the main phase of the study and lung cancer patients after surgery for the validation phase. The work was carried out in two university hospitals located in Osaka prefecture, Japan from July 2005 to August 2005 (breast cancer) and from February 2006 to April 2006 (lung cancer). Before initiation of this survey, the study protocol was examined and approved by the institutional review boards.

Both samples of breast cancer and lung cancer included patients with an Eastern Cooperative Oncology Group performance status of 1 or 2 and those who underwent surgery. On the face sheet of the questionnaire for the development phase, a single sentence explained that ethical notification and return of the questionnaire were regarded as consent to participate in our study, and patients were asked to return the questionnaires anonymously. For validation phase, we obtained written informed consent for participation in the study. Each patient was asked to complete two questionnaires in one month.

Instrument development

The questionnaire for cancer-related worry was developed by the authors and called the Brief Cancer-Related Worry Inventory (BCWI). We pooled items to describe patients' worries, concerns, unmet needs, and stressors by review of related articles [2-12]. The main domain of the items were *cancer itself, disability, effect of cancer treatment, side effects, physical distress, psychological distress, change of appearance, sexual issues, medical uncertainty, death, social support from family and medical staff, work, and economic status*. As we intended to develop a brief and clinically useful instrument, the developed items underwent intensive review of their content and clinical validity and modification of their verbal expressions by an oncologist, a nurse manager of a cancer ward, two psychiatrists, and two psychologists who were experienced in psycho-oncology practice and research. Finally, 15 items were selected through this procedure (see Table 2). The participants were asked to rate their degree of worry about the 15 items on an 11-point Likert-type scale, ranging from 0 (not at all worried) to 100 (extremely worried).

Development of a scale for cancer-related worry

Measures

We used the Japanese version [23] of the HADS [24] to assess patients' depression and anxiety. The HADS has 14 items in two question groups, one each on anxiety and depression, and each question is rated from 0 to 3.

The Japanese version of the Impact of Event Scale-Revised (IES-R) [25,26] was assessed for Posttraumatic Stress Disorder (PTSD) symptoms based on DSM-IV criteria. Respondents were asked to rate each item in relation to their cancer and its treatment, referring to their condition over the previous seven days. IES-R assesses three dimensions of PTSD symptoms: avoidance, intrusion, and hypervigilance.

Finally, the Japanese version of the Medical Outcomes Study Short Form-8 (SF-8) [27,28] was used to evaluate health-related quality of life. Each of the 8 items assesses a different dimension of health: general health, physical functioning, role

physical, bodily pain, vitality, social functioning, mental health, and role emotional. The SF-8 provides summary scores for Physical Component Scales (PCS) and Mental Component Scales (MCS). Scores from each item or summary measurements range from 0-100, with higher scores indicating better health.

Statistical analyses

Descriptive statistics were calculated for 15 items for the BCWI. As no largely skewed items were found, we performed an exploratory factor analysis using the maximum likelihood method and the promax rotation methods. After extracting factor structure, we performed the confirmatory factor analysis using the maximum likelihood method to test whether our factor structure fit the data. After calculating total scores of each subscale of the cancer-related worry scale, the correlation analyses were performed to evaluate convergence and validity of discrimination among subscales of cancer-related worry, HADS, IES-R, and SF-8. We used multidimensional scaling analysis based on the Euclidean distance model of stimulus configuration of measures to graphically describe and cluster multiple relations and similarities among cancer-related worry, HADS, and IES-R using their standardized scores. This statistical method can visualize similarities of endorsements by making a matrix of correlation coefficients. Kruskal's stress values were used as a badness-of-fit measure, and the two dimensional solution was adopted because of its simplicity, and ease of interpretation. To test the reliability of the BCWI, we calculated Cronbach's alpha on both the main and validation phase data and intra-class correlation coefficients of scores in the validation phase for test-retest reliability. We conducted all statistical analyses using the SPSS software package

Table 1. Patients' background

	Development breast cancer N = 109		Validation lung cancer N = 20	
Age (years)				
Mean	54.5		65.6	
SD	11.4		8.8	
Gender				
Male	43	15.9%	16	41.5%
Female	45	18.3%	4	44.7%
Time since diagnosis (months)				
Mean	31.3		5.8	
SD	38.6		12.5	
Stage				
I	56	51.4%	12	60.0%
II	53	48.6%	0	0.0%
III			3	15.0%
Other			5	25.0%
Chemotherapy	58	14.8%	0	0.0%

Table 2. Factor loadings and mean score of Brief Cancer-Related Worry Inventory

	Factor 1 (future prospects)	Factor 2 (physical and symptomatic problems)	Factor 3 (social and interpersonal problems)	Mean	SD
(1) About whether cancer might get worse in the future	0.87	-0.09	0.05	53.70	31.70
(2) About cancer itself	0.84	0.09	-0.13	71.30	29.03
(3) About effect of current treatment	0.75	-0.26	0.27	38.50	28.99
(4) About life and death of oneself	0.69	0.21	-0.07	50.80	30.71
(5) About how to cope with cancer situation	0.57	0.32	0.05	41.00	25.35
(6) About mental status	0.55	0.34	-0.12	41.00	27.72
(7) About physical symptom	0.10	0.74	-0.08	37.60	29.93
(8) About side effect of cancer treatment	0.10	0.63	0.01	41.90	29.97
(9) About change of appearance	-0.03	0.62	0.23	37.80	31.19
(10) About sexual issues	-0.07	0.42	0.16	14.20	20.81
(11) About relationships with family members	-0.03	-0.06	0.88	18.40	25.50
(12) About doing job or house work	-0.18	0.34	0.65	31.80	31.19
(13) About relationships with medical staff	0.30	-0.03	0.48	20.00	23.01
(14) About the future of family members	0.35	0.04	0.42	39.50	30.74
(15) About economic problems	0.07	0.37	0.40	38.40	34.03

(version 11.0), except for the confirmatory factor analysis for which we used the EQS software package (version 5.6).

Results

Backgrounds of patients and distribution

Patients who satisfied the inclusion criteria and consented for enrollment in this study returned 112 responses in the development phase and 20 responses in the validation phase. Because 3 responses in the development phase were excluded due to more than 30% missing values, 109 responses in the development phase and 20 responses in the validation phase were finally analyzed. Table 1 summarizes the backgrounds of the patients in the development and validation phases.

Descriptive statistics of BCWI

Table 2 shows descriptive statistics of the 15 items in the BCWI. The item that had the highest mean score was 'worry for cancer itself' ($M = 71.3$), followed by 'worry for recurrence and metastasis' ($M = 53.7$) and 'worry for future life and death' ($M = 50.8$). The lowest scoring item was 'worry for sexual problems' ($M = 14.2$). The next lowest items were 'worry for family relationships' ($M = 18.4$) and 'worry for relationships with medical staff' ($M = 20.0$).

Factor structure of the BCWI

The exploratory factor analysis of the 15 items yielded a 3-factor structure. This solution was adopted because it was the only interpretable factor structure and its eigenvalue was >1.0 . The subscales were interpreted as (1) future prospects, (2) physical and symptomatic problems, and (3) social and interpersonal problems (Table 2). We then adopted a second-order factor structure with 15 items and 4 factors including a second-order factor, cancer-related worry, due to moderate correlations among 3 factors, consistency with the hypothesized concepts, and clinical validity for a confirmatory factor analysis. The fit indices for this model were acceptable: chi-square ($df = 87$) = 160.16, $P = 0.001$; GFI = 0.83; CFI = 0.92; RMSEA = 0.09. Figure 1 presents the factor structure of BCWI.

Internal consistency and test-retest reliability of BCWI

Table 3 summarizes the internal consistency (Cronbach's alpha coefficients) and test-retest reliability of the BCWI on the data obtained from the test-retest phase for lung cancer patients. The

BCWI had excellent internal consistency for both breast cancer and lung cancer samples and moderate and substantial test-retest reliability for the lung cancer sample.

Validity of the BCWI and discrimination form anxiety

Table 4 shows the correlations among BCWI, HADS, IES-R, and SF-8. There are significant and moderate correlations between subscales of BCWI, HADS, and IES-R ($r = 0.27-0.59$, $P < 0.01$), weak correlations between subscales of BCWI and PCS of SF-8 ($r = -0.28$ to -0.19 , $P < 0.05$), and moderate correlations with MCS ($r = -0.42$ to -0.43 , $P < 0.001$).

Figure 2 shows the structure of worry, anxiety, depression, intrusive, avoidance, and hyperarousal in BCWI, HADS, and IES-R using multidimensional scaling. The horizontal dimension and the vertical dimension successfully discriminate BCWI, HADS, and IES-R. The subscales of IES-R are located in the area defined by positive values both on the horizontal and vertical dimensions. The subscales of HADS were located in the negative area on the horizontal dimension and the positive area on the vertical. Three subscales of BCWI are located in the negative area on the vertical axis and the area near zero on the horizontal dimension. Kruskal's stress value ($= 0.14$) and proportion of variance of data ($= 0.89$) indicated that this solution was valid and accounted for more than 89% of the variance. The analysis showed that cancer-related worry is identifiable from anxiety, depression, and PTSD symptoms.

Discussion

We have successfully developed a brief instrument for the measurement of cancer-related worry of cancer patients (BCWI). The psychometric properties of the scale are acceptable. The reliability was shown by excellent internal consistency (overall Cronbach's alpha coefficient = 0.87) and fair test-retest reliability (intra-class correlation coefficient = 0.69). Construct validity was established by confirmatory factor analysis. In addition, the 15 items of the BCWI did not have any ceiling or floor effects. The feasibility of the scale was established with two different samples, breast cancer and lung cancer patients. Therefore, the BCWI has necessary and sufficient constructs for a useful compact scale with reliability and validity.

The scale has three subscales, namely future prospects, physical and symptomatic problems, and social and interpersonal problems. The themes of the subscales were consistent with previously identified domains in the concern or unmet need studies [2-12]. The future prospect subscale repre-

Development of a scale for cancer-related worry

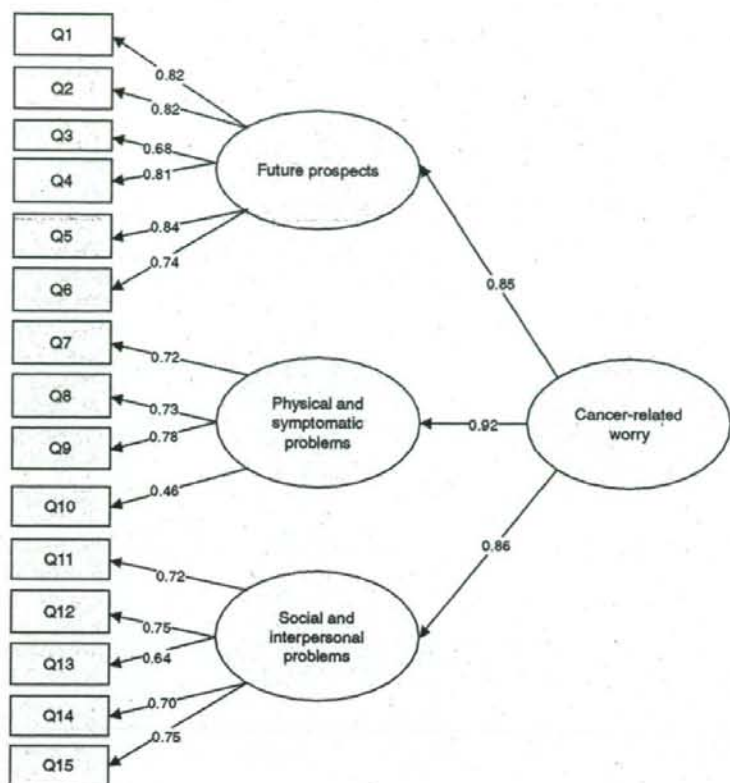


Figure 1. The factor structure of BCWI. Parameter estimates are standardized. Model Fit index: Chi-square(87) = 160.16, $P = 0.00$; GFI = 0.83; CFI = 0.92; RMSEA = 0.09. Numbers of items correspond to those in Table 2

Table 3. Reliability of the Brief Cancer-Related Worry Inventory

	Cronbach alpha coefficient ^a	Cronbach alpha coefficient ^b	Test-retest ICC ^c
Future prospects	0.90	0.86	0.75
Physical and symptomatic problems	0.77	0.69	0.53
Social and interpersonal problems	0.83	0.75	0.54
Cancer-related worry	0.87	0.92	0.69

^aDevelopment phase (breast cancer).

^bValidation phase (lung cancer).

^cIntra-class correlation coefficients.

sents the worries for future events, outcomes, or uncertainty. The mean scores of the items in this subscale were higher than that of other subscales. A previous study reported that uncertainty of hospitalized patients was correlated with stress [29]. These studies indicated that future prospects including uncertainty and perceived negative outcomes or consequences of cancer comprise a central concept of cancer-related worry. Physical

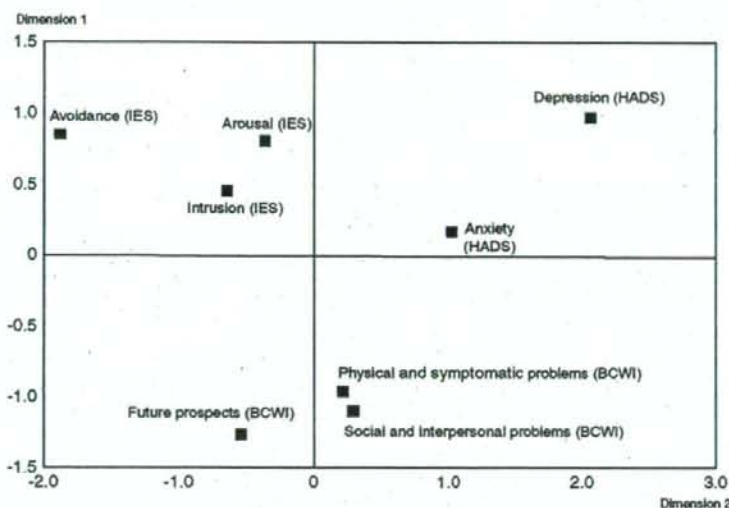
and symptomatic problems covered the domain of actual problems caused by cancer itself: physical symptoms, side effects of treatments, changes of appearance, and sexual issues. For our development data, test-retest reliability was lower than other subscales of BCWI. This indicates that this subscale is sensitive to physical and symptomatic changes of the patients and has content validity. Physical and symptomatic changes were found to be primary concerns of cancer patients in several studies [2-5], and controlling them was a primary purpose of palliative care or supportive care in ordinary medical treatment. Thus, changes of the score in this domain will correspond with the actual outcome of palliative treatments. *Social and interpersonal problems* covered secondary problems caused by cancer, including problems in interpersonal relationships with family members or medical staff, problems on the job, house work, and economic problems. Although these worries will not be influenced directly by cancer itself or cancer treatment, they may be very difficult issues for cancer patients to cope with or solve. Several forms of psychosocial intervention might be effective for these kinds of problems.

Table 4. Intercorrelations between Brief Cancer-Related Worry Inventory and other measures

	1	2	3	4	5	6	7	8	9
1. Future prospects (BCWI)	§								
2. Physical and symptomatic problems (BCWI)	0.65***	§							
3. Social and interpersonal problems (BCWI)	0.64***	0.66***	§						
4. Anxiety (HADS)	0.57***	0.48***	0.59***	§					
5. Depression (HADS)	0.27**	0.45***	0.39***	0.58***	§				
6. Intrusion (IES-R)	0.55***	0.56***	0.56***	0.58***	0.40***	§			
7. Avoidance (IES-R)	0.45***	0.40***	0.36***	0.35***	0.19*	0.65***	§		
8. Arousal (IES-R)	0.48***	0.56***	0.54***	0.57***	0.43***	0.77***	0.54***	§	
9. Physical component scales (SF8)	-0.19*	-0.28**	-0.18	-0.23*	-0.40***	-0.27**	-0.13	-0.31**	§
10. Mental component scales (SF8)	-0.41***	-0.34***	-0.42***	-0.55***	-0.42***	-0.58***	-0.32**	-0.60***	0.19*

* $P < 0.05$, ** $P < 0.01$, *** $P < 0.001$.

BCWI, Brief Cancer-related Worry Inventory; HADS, Hospital Anxiety and Depression Scale; IES-R, Impact of Event Scale Revised; SF8, Medical Outcomes Study Short Form-8.

**Figure 2.** The structure of similarities among subscales of BCWI, HADS, and IES. Kruskal's stress value (= 0.14) and proportion of variance of data (= 0.89). BCWI, Brief Cancer-Related Worry Inventory; HADS, Hospital Anxiety and Depression Scale; IES-R, Impact of Event Scale Revised; SF8, Medical Outcomes Study Short Form-8

The finding that the BCWI was moderately correlated with HADS, IES-R, and SF-8 indicates that the scale has convergent validity. However, when we investigated the detailed differences and similarities among the scales by multidimensional scaling, we found that the distance between the subscales of BCWI and HADS-anxiety was similar to that between BCWI and HADS-depression and their directions were opposite (Figure 2). In addition to, the BCWI subscales were graphically different from the intrusion, avoidance, and arousal subscales of IES-R. If the distance between depression and anxiety in HADS is enough to discriminate two different emotional conditions, the subscales of BCWI were discriminable from HADS-anxiety and all the subscales of IES-R. Therefore, cancer-related worry that the BCWI measures is an interrelated but different and

emotional construct discriminable from anxiety, depression, and PTSD symptoms.

Among discriminable aspects of the BCWI, the difference between worry and anxiety shows that patients with high cancer-related worry are not necessarily in a severely anxious status. In addition, the BCWI can evaluate the contents of each worry and their individual magnitudes, whereas the HADS-anxiety subscale can only measure the intensity of anxious states. This means that measurement of cancer-related worry by BCWI is valuable to clinical practice. For example, assessment of the type of cancer-related worry will contribute to formulation of a psychological intervention for the cancer patient, especially interventions using the problem-solving technique [30,31], because in the earlier stage of the problem-solving technique, making problem-lists is needed

for identifying the problem and setting a priority for solution. The BCWI will be helpful for patients to create their problem-list in a very structured and effective way.

The limitations to this study include the small and limited sample. We developed the items using a breast cancer sample ($N = 112$) and confirmed internal consistency and test-retest reliability using a lung cancer sample ($N = 20$). These samples are different from samples used in the development phase of this scale. As we used only two different cancer samples, this may limit validity for using the BCWI for patients with other kinds of cancer. However, we suppose that because the items of this scale were developed by reference to a broad range of the articles concerning unmet need, concerns, and stressors of cancer patients, the items in the scale are sufficiently general for application to other cancers.

In conclusion, our study succeeded in developing and confirming the validity and reliability of a scale for assessment of cancer-related worry, the so-called BCWI. The BCWI has only 15 items that enable a brief evaluation of the content and the magnitude of cancer-related worry of cancer patients. The study also confirmed that aspects of cancer-related worry are discriminable from anxiety, depression, and PTSD symptoms. However, to reach a final conclusion about differences in complicated emotions and usefulness for clinical practice in cancer care, further empirical work using the prospective design and academic discussion will be needed.

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References

1. Stark DP, House A. Anxiety in cancer patients. *Br J Cancer* 2000;83(10):1261-1267.
2. Sanson-Fisher R, Girgis A, Boyes A, Bonevski B, Burton L, Cook P. The unmet supportive care needs of patients with cancer. *Support Care Rev Group. Cancer* 2000;88(1):226-237.
3. Soothill K, Morris SM, Harman J, Francis B, Thomas C, McIlmurray MB. The significant unmet needs of cancer patients: probing psychosocial concerns. *Support Care Cancer* 2001;9(8):597-605.
4. Foot G, Sanson-Fisher R. Measuring the unmet needs of people living with cancer. *Cancer Forum* 1995;19:131-135.
5. Steginga SK, Occhipinti S, Dunn J, Gardiner RA, Heathcote P, Yaxley J. The supportive care needs of men with prostate cancer (2000). *Psycho-Oncology* 2001;10(1):66-75.
6. Akechi T, Okuyama T, Sugawara Y, Nakano T, Shima Y, Uchitomi Y. Major depression, adjustment disorders, and post-traumatic stress disorder in terminally ill cancer patients: associated and predictive factors. *J Clin Oncol* 2004;22(10):1957-1965.
7. Hill KM, Amir Z, Muers MF, Connolly CK, Round CE. Do newly diagnosed lung cancer patients feel their concerns are being met? *Eur J Cancer Care (Engl)* 2003; 12(1):35-45.
8. Harrison J, Maguire P, Pitceathly C. Confiding in crisis: gender differences in pattern of confiding among cancer patients. *Soc Sci Med* 1995;41(9):1255-1260.
9. Farrell C, Heaven C, Beaver K, Maguire P. Identifying the concerns of women undergoing chemotherapy. *Patient Educ Couns* 2005;56(1):72-77.
10. Heaven CM, Maguire P. The relationship between patients' concerns and psychological distress in a hospice setting. *Psycho-Oncology* 1998;7(6):502-507.
11. Heaven CM, Maguire P. Disclosure of concerns by hospice patients and their identification by nurses. *Palliat Med* 1997;11(4):283-290.
12. Carver CS, Pozo-Kaderman C, Price AA et al. Concern about aspects of body image and adjustment to early stage breast cancer. *Psychosom Med* 1998;60(2): 168-174.
13. American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders* (3rd edn). APA: Washington, DC, 1987.
14. Wells A, Carter K. Preliminary tests of a cognitive model of generalized anxiety disorder. *Behav Res Ther* 1999;37(6):585-594.
15. Mathews A. Why worry? The cognitive function of anxiety. *Behav Res Ther* 1990;28(6):455-468.
16. Hay JL, Buckley TR, Ostroff JS. The role of cancer worry in cancer screening: a theoretical and empirical review of the literature. *Psycho-Oncology* 2005;14(7):517-534.
17. Consedine NS, Magai C, Krivoshekova YS, Ryzewicz L, Neugut AI. Fear, anxiety, worry, and breast cancer screening behavior: a critical review. *Cancer Epidemiol Biomarkers Prev* 2004;13(4):501-510.
18. Andersen MR, Smith R, Meischke H, Bowen D, Urban N. Breast cancer worry and mammography use by women with and without a family history in a population-based sample. *Cancer Epidemiol Biomarkers Prev* 2003;12(4):314-320.
19. Andersen MR, Peacock S, Nelson J et al. Worry about ovarian cancer risk and use of ovarian cancer screening by women at risk for ovarian cancer. *Gynecol Oncol* 2002;85(1):3-8.
20. Cohen L, Fouladi RT, Babiak RJ et al. Cancer worry is associated with abnormal prostate-specific antigen levels in men participating in a community screening program. *Cancer Epidemiol Biomarkers Prev* 2003; 12(7):610-617.
21. Mathews A, Ridgeway V, Warren R, Britton P. Predicting worry following a diagnosis of breast cancer. *Psycho-Oncology* 2002;11(5):415-418.
22. Stefanek ME, Shaw A, DeGeorge D, Tsottles N. Illness-related worry among cancer patients: prevalence, severity, and content. *Cancer Invest* 1989;7(4):365-371.
23. Kitamura T. The Hospital Anxiety and Depression Scale. *Arch Psychiatr Diagn Clin Eval* 1993;4:371-372 (in Japanese).
24. Zigmund AS, Snaith RP. The Hospital Anxiety and Depression Scale. *Acta Psychiatr Scand* 1983; 67(6):361-370.
25. Weiss DS, Marmar CR. The impact of event scale-revised. In *Assessing Psychological Trauma and PTSD*, Wilson JP, Keane TM (eds). Guilford Press: New York, 1997; 399-411.
26. Asukai N, Kato H, Kawamura N et al. Reliability and validity of the Japanese-language version of the Impact of Event Scale-Revised (IES-R-J): four studies of

- different traumatic events. *J Nerv Ment Dis* 2002;190(3):175-182.
27. Ware JE, Kosinski M, Dewey JE, Gandek B. How to Score and Interpret Single-Item Health Status Measures: A Manual for Users of the SF-8 TM Health Survey. QualityMetric Inc: Lincoln, 1999.
 28. Fukuhara S, Suzukamo Y. Manual of the SF-8 Japanese Version. Institute for Health Outcomes and Process Evaluation Research: Kyoto, 2004.
 29. Mishel MH. The measurement of uncertainty in illness. *Nurs Res* 1981;30(5):258-263.
 30. Nezu AM, Nezu CM, Felgoise SH, McClure KS, Houts PS. Project genesis: assessing the efficacy of problem-solving therapy for distressed adult cancer patients. *J Consult Clin Psychol* 2003;71(6):1036-1048.
 31. Fawzy FI. A short-term psychoeducational intervention for patients newly diagnosed with cancer. *Support Care Cancer* 1995;3(4):235-238.

Original Article

Good Death Inventory: A Measure for Evaluating Good Death from the Bereaved Family Member's Perspective

Mitsunori Miyashita, RN, PhD, Tatsuya Morita, MD, Kazuki Sato, RN, MHIthSci, Kei Hirai, PhD, Yasuo Shima, MD, and Yosuke Uchitomi, MD, PhD

Department of Adult Nursing/Palliative Care Nursing (M.M., K.S.), School of Health Sciences and Nursing, Graduate School of Medicine, University of Tokyo, Tokyo; Department of Palliative and Supportive Care, Palliative Care Team and Seirei Hospice (T.M.), Seirei Mikatahara Hospital, Shizuoka; Center of the Study for Communication Design, Psychology and Behavioral Sciences (K.H.), Graduate School of Human Sciences, and Department of Complementary and Alternative Medicine (K.H.), Graduate School of Medicine, Osaka University, Osaka; Department of Palliative Medicine (Y.S.), Tsukuba Medical Center Hospital, Ibaraki; and Psycho-Oncology Division (Y.U.), Research Center for Innovative Oncology, National Cancer Center Hospital East, Chiba, Japan

Abstract

The aim of this study was to develop a measure for evaluating good death from the bereaved family member's perspective, and to examine the validity and reliability of the assessment. A cross-sectional anonymous questionnaire was administered to bereaved family members of cancer patients who had died in a regional cancer center from September 2004 to February 2006. We measured the Good Death Inventory (GDI), Care Evaluation Scale, and an overall care satisfaction scale. A retest was conducted one month after sending the questionnaire. Of the 344 questionnaires sent to bereaved family members, 189 responses were analyzed (57%). A factor analysis of the responses to the GDI identified 10 core domains: "environmental comfort," "life completion," "dying in a favorite place," "maintaining hope and pleasure," "independence," "physical and psychological comfort," "good relationship with medical staff," "not being a burden to others," "good relationship with family," and "being respected as an individual." Eight optional domains also were identified: "religious and spiritual comfort," "receiving enough treatment," "control over the future," "feeling that one's life is worth living," "unawareness of death," "pride and beauty," "natural death," and "preparation for death." The GDI had sufficient concurrent validity with the Care Evaluation Scale and overall care satisfaction, sufficient internal consistency ($\alpha = 0.74-0.95$), and acceptable test-retest reliability ($ICC = 0.38-0.72$). Finally, we developed a short version of the GDI. The GDI is a valid scale to measure end-of-life care comprehensive outcomes from the bereaved family member's perspective in Japan. *J Pain Symptom Manage*

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Graduate School of Medicine, University of Tokyo, 7-3-1 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan. E-mail: miyashita-ky@umin.net

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Key Words

Palliative care, end-of-life care, neoplasms, hospice, questionnaires, measures, good death

Introduction

One of the most important goals of palliative care is achieving a "good death" or a "good dying process." In Western countries, elaborate efforts have been devoted to conceptualizing a good death, using qualitative research.¹⁻⁶ Quantitatively, Steinhäuser et al. have elucidated important factors that influence the end of life.^{7,8} In addition, Steinhäuser et al. have measured the achievement of a good death by terminally ill patients.^{9,10}

However, interviewing or administering a questionnaire to vulnerable terminally ill patients is burdensome, and nonresponse because of severe illness might result in biased conclusions. Therefore, many studies to evaluate end-of-life care have been conducted with bereaved family members.¹¹⁻¹⁶ The evaluation of end-of-life care from the bereaved family member's perspective requires valid and reliable measures. Some instruments have been developed for this purpose, such as the Toolkit for After Death Interview,¹⁷ Quality of Death and Dying questionnaire for end-of-life care settings,¹⁸ and the modified Quality of Death and Dying questionnaire for intensive care units.¹⁵ In Japan, Morita et al. developed a satisfaction scale for bereaved family members¹⁹ and the Care Evaluation Scale (CES) focusing on structure and process of end-of-life care.²⁰

In Japan, however, only a few studies have investigated the elements that constitute a good death: a qualitative study of hospice nurses,²¹ a small investigation of advanced cancer patients,²² and an observational study of patients.²³ To fulfill the goals of palliative care in Japan, it is important to conceptualize what constitutes a good death in Japan. Therefore, as a first step, we conducted a nationwide qualitative study to explore attributes of a good death in Japan; this included a total of 63 participants, including advanced cancer patients and their families, physicians, and nurses.²⁴ For the next step, we conducted a quantitative

study to determine what attributes were considered necessary for a good death, using a large nationwide sample of the general population and bereaved family members in Japan.²⁵ In this study, we identified 18 domains contributing to a good death for Japanese subjects, including 10 core domains that most Japanese consistently rated as important and eight optional domains that were not as consistently rated as important by individuals.²⁵

As a third step, the aim of this study was to develop a measure for evaluating good death from the bereaved family member's perspective based on our previous investigations, and to examine the validity and reliability of this new measure in Japan.

Methods

Participants and Procedures

A cross-sectional anonymous questionnaire was administered to bereaved family members of cancer patients who had died in a regional cancer center's general wards and inpatient palliative care unit (PCU) in Ibaraki prefecture, Japan. The Japanese Ministry of Health, Labor, and Welfare has strongly supported dissemination of specialized palliative care services, with coverage of PCUs by National Medical Insurance since 1990. The number of PCUs has dramatically increased from five in 1990 to 163 in 2006. In contrast, the growth of home-based palliative care programs has been slow, as inpatient palliative care teams were not covered by National Medical Insurance until 2002. Therefore, the most common type of specialized palliative care service in Japan is the PCU. Although the number of PCUs has increased, they cover only 5% of all cancer deaths. In 2004, only 6% of cancer deaths occurred in the home and over 80% of cancer deaths occurred on general wards. Therefore, death on general wards is an important issue in Japan.

To find potential participants, we identified bereaved family members of patients who died from September 2004 to February 2006. The inclusion criteria were as follows: (1) patient died in PCU or died on the general ward from lung cancer or gastrointestinal cancer, (2) patient was aged 20 years or more, and (3) patient was hospitalized at least three days. The exclusion criteria were as follows: (1) participant was recruited for another questionnaire survey for bereaved family members, (2) participant would have suffered serious psychological distress as determined by the primary physician, (3) cause of death was treatment-related or due to injury, (4) there was no bereaved family member who was aged 20 years or more, (5) participant was incapable of replying to a self-reported questionnaire, and (6) participant was not aware of the diagnosis of malignancy.

We mailed questionnaires to potential respondents in October 2006 and a reminder was sent in November 2006 to those who did not respond. We asked that the primary caregiver complete the questionnaire. If the respondents did not want to participate in the survey, they were asked to return the questionnaire with "no participation" indicated, and a reminder was not mailed to them. To examine test-retest reliability, we sent the same questionnaire one month after sending the original questionnaire. The ethical and scientific validity of this study was approved by the institutional review boards of Tsukuba Medical Center Hospital.

Measurements

Good Death Inventory. The Good Death Inventory (GDI) evaluates end-of-life care from the bereaved family member's perspective. Seventy potential attributes of a good death were asked, using a seven-point Likert scale (1: absolutely disagree, 2: disagree, 3: somewhat disagree, 4: unsure, 5: somewhat agree, 6: agree, 7: absolutely agree). The attributes were generated based on a previous qualitative study,²⁴ quantitative study,²⁵ and literature review.^{7,8,13,15,17-20} In the qualitative study, we found 58 attributes of a good death in Japan.²⁴ In the following quantitative study, we asked 57 questions based on the previous qualitative study and literature review. Finally, we concluded, using factor analysis and Cronbach's alpha coefficients, that the

Japanese concept of a good death was constituted by 18 domains.²⁵ We then composed three or more questions for each of the 18 domains. Therefore, we assumed there were 18 hypothetical domains based on the results of previous studies. We calculated the domain score by summing up attributes. A high score indicated the achievement of a good death in each domain. Total scores were calculated in three ways: a total of all attributes, a total of 10 core domain attributes, and a total of eight optional domain attributes. The questionnaire that was finally adopted is described in the Appendix.

The face validity was evaluated by two physicians, two nurses, and two lay persons. The GDI was generated based on the previous qualitative study with 63 participants²⁴ and a nationwide quantitative study with 3,061 participants.²⁵ In addition, we conducted a literature review and fully discussed the content validity among co-researchers. This process ensured the content validity of our questionnaire.

CES, Short Version. We used the CES, short version, to examine concurrent validity. The CES was developed to measure end-of-life care from the bereaved family member's perspective especially focusing on structure and process of care.²⁰ The original version of the CES was 10 domains (help with decision making for patient, help with decision making for family, physical care by physician, physical care by nurse, psycho-existential care, environment, cost, availability, coordination of care, and family burden), with 28 attributes. The validity and reliability of this scale have been tested.²⁰ The questionnaire was designed so that the respondent evaluated the structure and process of end-of-life care by rating the necessity of improvement for each item on a six-point Likert scale from 1: improvement is not necessary to 6: improvement is highly necessary. The score was transformed to a 0-100 point scale, with a high score indicating excellent care. The short version of the CES consisted of 10 items from each domain and validity and reliability were confirmed.

Overall Care Satisfaction. We asked the participants about their overall care satisfaction in order to examine concurrent validity. The question was, "Overall, were you satisfied with the care in the hospital?" The participant was asked to answer using a six-point Likert scale from 1: absolutely dissatisfied to 6: absolutely satisfied.