

Several previous studies have investigated the association between lung cancer patient's psychosocial factors and survival. For example, Faller *et al.* reported a significant association between depressive coping/interviewer-rated emotional distress and a shorter survival period [13–15]. Nakahara *et al.* also demonstrated a significant association between mental state, as assessed using an egogram, and survival [16]. Other groups have reported significant associations between survival and depression [17], suicidal ideation [17], personality [18], psychosocial well-being [19], social support [19], and symptom distress [20], although some studies failed to clarify a significant influence of factors such as marital status [21], depression [15,22], social support [21], 24-h urinary cortisol level (used as an indicator of physiological or psychological stress) [23], self-reported psychological distress [13,14,20], and concerns [20]. On the other hand, most of these previous studies were flawed by severe methodological limitations, including a retrospective design [18,20], a short or unclear follow-up period (e.g. less than 1 year) [17,18], a small sample (e.g. less than 100 patients) [17,20], the lack of controls for well-established prognostic factors (especially because several biomedical factors have been identified as definite/possible prognostic factors among patients with non-small cell lung cancer (NSCLC) [24], and adjustments for these biomedical factors should be performed when evaluating other prognostic factors [25]) [13,14,18,20], and the assessment of variables after treatment (psychosocial factors should be evaluated at the same time as other biomedical factors, before treatment) [18,20]. In addition, none of the previous studies checked the stability of the investigated variables, although many psychosocial factors can change during the course of a patient's illness, and none of the studies simultaneously investigated a broad range of psychosocial factors, including diagnosable depression—known to be the most common psychiatric disorder, using a reliable measure, such as a structured clinical interview.

The purpose of the present study was to use a more rigorous study design to investigate the association between relevant psychosocial factors and patient survival after a diagnosis of inoperable NSCLC.

Patients and methods

Patients

The subjects were consecutive patients with NSCLC who had been newly diagnosed at the Thoracic Oncology Division, National Cancer Center Hospital East (NCCHE), Japan, between August 1996 and January 1998. Patients were

included in the study if they met all of the following criteria: (1) histologically or cytologically confirmed NSCLC; (2) diagnosis of unresectable cancer (clinical stage unresectable IIIA, IIIB, or IV); (3) informed of their lung cancer diagnosis; (4) a performance status (PS) of between 0 and 2, according to the Eastern Cooperative Oncology Group criteria; (5) follow-up care at the Thoracic Oncology Division of the NCCHE; (6) 18 years of age or older; (7) not too ill to participate in an interview or complete questionnaires; (8) absence of brain metastasis, as confirmed using brain CT or MRI; (9) ability to provide written consent; (10) absence of cognitive impairment, such as delirium or dementia (if a subject was suspected of having a cognitive impairment, cognitive function was evaluated using the Mini Mental State Examination (MMS); only subjects with an MMS score of 24 or more were allowed to participate in the study [26]); (11) no history of previous anticancer treatment within 5 years; and (12) no active concomitant cancer.

This study was approved by the Institutional Review Board and the Ethics Committee of the National Cancer Center of Japan and was conducted in accordance with the Helsinki Declaration. Written informed consent was obtained from each subject before enrollment into this study.

Assessment of psychosocial factors

We investigated each patient's coping with cancer, psychological distress, psychiatric disorders, and social support as potential psychosocial predictors of survival. These factors, other than the psychiatric disorders, were evaluated twice (after diagnosis but before treatment: baseline (T1), and 2 months after T1; T2) to check the stability of the factors. An assessment of psychiatric disorders was not conducted at T2 to avoid unnecessary increases of the patient's burden. The measures at baseline were investigated as potential prognostic factors.

Coping with cancer

Each patient's coping with having cancer was measured using the Japanese version of the Mental Adjustment to Cancer (MAC) scale [27]. The MAC scale consists of five subscales. Our previous study revealed that the Japanese version of the MAC scale was valid and reliable [27]. Among the subscales, we used fighting spirit and helplessness/hopelessness, which were shown to be potential prognostic factors in a previous study [28].

Psychological distress

Psychological distress was evaluated using the Profile of Mood States (POMS) [29]. The POMS is a 65-item self-rated scale for measuring mood

disturbance. The POMS is a widely used, reliable measure of emotional distress that has been validated in cancer patients and demonstrated to be reliable for Japanese people [30]. The Total Mood Disturbance (TMD) scale of the POMS, which is the sum of the emotional state subscales, was used. A higher TMD indicates greater emotional distress.

Psychiatric disorders

A trained psychiatrist (T.A.) conducted a Structured Clinical Interview based on the Diagnostic and Statistical Manual of Mental Disorders, 3rd edition-revised [31] to evaluate major depression and adjustment disorders in each patient. In addition, the patients were asked to complete the Hospital Anxiety and Depression scale (HADS) at baseline. The HADS is a 14-item self-reported questionnaire consisting of an anxiety and depression subscale; the total score can range from 0 to 42 [32]. Higher scores indicate more severe depression and anxiety. The Japanese version of the HADS was validated in a cancer population, and the optimal cutoff point for screening for adjustment disorder and major depressive disorder was 10/11 [33].

Social support

The patients' use of confidants (number of confidants and satisfaction with confidants) was used as an indicator of social support factors. This information was obtained in a structured interview, as described previously [34]. In the interview, the patients were asked the number of people they had confided in since being diagnosed with cancer and how satisfied they were with their interactions with these confidants. When the patients had not confided in anyone, they were asked about their degree of satisfaction in not having done so. The patients' responses ranged from 1 to 7: 1, 'very dissatisfied'; 2, 'fairly dissatisfied'; 3, 'slightly dissatisfied'; 4, 'neither'; 5, 'somewhat satisfied'; 6, 'fairly satisfied'; and 7, 'very satisfied'.

Sociodemographic and biomedical factors

Sociodemographic factors (age, gender, marital status, education, household size, and employment status) were investigated using a structured interview at baseline. PS (assessed using the Eastern Cooperative Oncology Group criteria) was also investigated at baseline. In addition, the patient was asked about weight loss during the previous 6 months during the baseline interview. Blood laboratory tests (albumin level, hemoglobin level, leukocyte count, platelet count, and lactate dehydrogenase (LDH) level) were performed at the time of cancer diagnosis. (These biological factors were

evaluated because they are definite/possible prognostic factors for NSCLC, as mentioned above.) Information on clinical stage and anticancer treatment were obtained from the patients' charts. Smoking status and alcohol consumption were not assessed in the study.

Statistical analysis

Survival was defined as the interval between the date of the pathological diagnosis of lung cancer and the date of death or the date of the last follow-up information for surviving patients. Survival was examined at 2 years after the study enrollment period. In addition to the psychosocial factors, sex, ECOG PS, disease stage, histology, albumin level, hemoglobin level, leukocyte count, platelet count, LDH level, weight loss, and the use of chemotherapy were analyzed. These factors include all the definite and/or possible prognostic factors of NSCLC other than biologic factors, such as oncogenes (e.g. ras, p53, etc.). All factors except for sex, treatment factors, clinical stage, and PS were treated as continuous variables (clinical stage and PS were treated as ordinal variables) [35]. The survival curves were estimated according to the Kaplan-Meier method. Because the Kaplan-Meier analysis indicated that there were a total of 108 events (deaths), up to approximately 11 covariates could be entered into the regression analysis for prognostic prediction [36]. We investigated the correlation among psychosocial factors; when a statistically significant correlation with a correlation coefficient of over 0.30 was observed, more clinically relevant factors were retained. Correlation coefficients of over 0.30 were obtained for the following pairs: helplessness/hopelessness and TMD, helplessness/hopelessness and HADS, and HADS and satisfaction with confidants. We prioritized TMD and satisfaction with confidants from a clinical point of view. Finally, a total of five psychosocial factors (fighting spirit, TMD, major depression, number of confidants, and satisfaction with confidants) were chosen for further investigation. Regarding biomedical factors, two definite prognostic factors (PS and disease stage) were compulsorily entered for adjustment [24]. As for other possibly relevant biomedical factors, we investigated the correlations among the factors and if a statistically significant correlation with a correlation coefficient over 0.30 was observed, more clinically relevant factors were retained. Correlation coefficients of over 0.30 were obtained for the following pairs: leukocyte count and platelet count, hemoglobin level and platelet count, hemoglobin level and albumin level, and platelet count and albumin level. We prioritized hemoglobin from clinical point of view. Finally, a total of six biomedical factors (PS, disease stage, histology, hemoglobin, serum LDH,

and chemotherapy) were retained for further adjustment. Univariate and multivariate Cox proportional hazards regression models were used to determine the relationships between the investigated variables and survival. Biomedical and psychosocial variables that proved significant in the univariate analysis were simultaneously entered into the multivariate Cox regression, while PS and disease stage were compulsorily entered into the multivariate analysis regardless of the results of the univariate analysis. To explore the stability of the investigated psychosocial factors, except for the presence of the psychiatric diagnosis assessed by the psychiatric diagnostic interview, Pearson correlation coefficients or the concordance rate between T1 and T2 were investigated. A *P* value of less than 0.05 was adopted as the significance level in all of the statistical analyses, and all reported *P* values were two-tailed. All statistical procedures were conducted using the SPSS 10.0J version software for Windows (SPSS Inc., 2003).

Results

Characteristics of the participants

During the study entry period, 230 cases of unresectable NSCLC were newly diagnosed; 79 patients were found to be ineligible for enrollment in the study (brain metastasis, *n* = 44; illness too severe, *n* = 16; cognitive impairment, *n* = 8; active concomitant cancer, *n* = 4; not informed of the diagnosis, *n* = 3; PS of 3 or 4, *n* = 3; illiteracy, *n* = 1). Among the remaining 151 eligible patients, 21 patients refused to participate in the study and 8 patients could not be contacted; thus, 122 patients ultimately participated. No significant differences in age, sex, marital status, employment, histology, or clinical stage were observed between the participants (*n* = 122) and the non-participants (*n* = 21); however, the non-participants had significantly lower PSs than the participants (*P* = 0.005).

The patient characteristics are shown in Table 1. About half of the subjects were diagnosed as having stage IV lung cancer, and the overall median survival period was approximately 8.5 months. A total of six patients suffered from major depression. After a 2-year follow-up period, 108 patients had died. The survival data were censored for the remaining 14 patients.

A comparison of the survival of patients with various biomedical and psychosocial factors using a univariate analysis is shown in Table 2. Among the psychosocial factors, none of the investigated factors, including coping with cancer, psychological distress, psychiatric disorders, and social support, were significantly associated with

Table 1. Patient characteristics (*n* = 122)

		No (%)
Age (years)	Mean ± SD	62 ± 9
	Median (range)	64.5 (40–82)
Sex	Male	90 (74)
Marital status	Married	107 (88)
Education	< 10 y	62 (51)
Employment status	Full-time	34 (28)
	Part-time	5 (4)
	Housewife	15 (12)
	Retired	40 (33)
	Others	28 (23)
Household size	Living alone	8 (7)
Profile of Mood States (Total Mood Disturbance)	Mean ± SD	34.3 ± 33.3
	Median	27
Performance Status*	0	12 (10)
	1	104 (85)
	2	6 (5)
Histology	Adenocarcinoma	81 (64)
	Squamous cell	31 (25)
	Large cell	9 (7)
	Adenosquamous	1 (1)
Disease stage	III A	4 (3)
	III B	59 (48)
	IV	59 (48)
Survival (months)	Mean	11
	Median	8.6
	25 percentile	5.4
	75 percentile	15.2

*As defined by the Eastern Cooperative Oncology Group criteria.

Table 2. Comparison of the survival of patients with various biomedical and psychosocial factors—univariate Cox proportional regression analyses

Variable	Coefficient	SE	Hazards ratio (95% CI)	P
Performance Status*	0.49	0.31	1.63 (0.89–2.99)	0.11
Disease stage	0.36	0.19	1.43 (0.99–2.07)	0.06
Histology (squamous cell)	0.34	0.22	1.40 (0.91–2.16)	0.13
Hemoglobin (g/dl)	-0.09	0.05	0.92 (0.83–1.02)	0.11
Serum LDH (IU/l)	0.001	0.000	1.001 (1.000–1.001)	0.001
Treatment (CTx)	-0.50	0.23	0.61 (0.39–0.96)	0.03
Fighting spirit ^b	0.02	0.02	1.02 (0.99–1.05)	0.16
Total Mood Disturbance ^c	0.002	0.003	1.002 (0.996–1.01)	0.53
Major depression	-0.23	0.46	0.79 (0.32–1.95)	0.61
Number of confidants	-0.01	0.02	0.99 (0.96–1.03)	0.71
Satisfied with confidant	-0.01	0.08	0.99 (0.84–1.16)	0.87

Psychosocial factors were assessed at after diagnosis but before treatment.

CI: confidence interval; LDH: lactate dehydrogenase; CTx: chemotherapy.

*As defined by the Eastern Cooperative Oncology Group criteria.

^bMental Adjustment Cancer Scale.

^cProfile of mood states.

the survival period. Among the biomedical factors, a higher serum LDH level and not receiving chemotherapy were significantly associated with shorter survival periods.

Table 3. Multivariate Cox proportional regression analysis

Variable	Coefficient	SE	Hazards ratio (95% CI)	P
Performance Status ^a	0.30	0.31	1.35 (0.74–2.48)	0.33
Disease stage	0.41	0.19	1.50 (1.03–2.19)	0.04
Serum LDH (IU/L)	0.001	0.000	1.001 (1.000–1.001)	0.001
Treatment (CTx)	-0.54	0.24	0.59 (0.37–0.93)	0.03

CI: confidence interval; LDH: lactate dehydrogenase; CTx: chemotherapy.
^aAs defined by the Eastern Cooperative Oncology Group criteria.

A multivariate Cox proportional regression analysis indicated that an advanced clinical stage, a higher serum LDH level, and not receiving chemotherapy were independently associated with a shorter survival period among patients with inoperable NSCLC (Table 3). In addition, we preliminarily conducted a stepwise Cox regression analysis (backward elimination), including the aforementioned five psychosocial factors and six biomedical factors. The findings also indicated that advanced disease stage, a high LDH level, and no chemotherapy were significantly associated with a shorter survival period (data not shown).

Regarding the stability of the psychosocial factors, our findings demonstrated that the correlation coefficients of the fighting spirit subscale of the MAC, the TMD of the POMS, the number of confidants, and the satisfaction with the confidants between T1 and T2 were 0.65 ($P < 0.001$), 0.54 ($P < 0.001$), 0.45 ($P < 0.001$), and 0.18 ($P = 0.06$), respectively. These findings suggested a moderate to high stability of most of the psychosocial factors other than the perceived satisfaction with social support.

Discussion

This is the first prospective cohort study to clarify the association between a broad range of psychosocial factors and survival among homogenous patients with advanced NSCLC. The present study has several advantages. First, we assessed most of the well-established biomedical prognostic factors, although the final analysis did not need to adjust for these factors. Second, we first investigated clinical depression using the most reliable method available (a structured clinical interview conducted by a trained psychiatrist). Third, we ascertained the stability of the psychosocial factors subsequent to the cancer diagnosis.

Our results demonstrated that psychosocial factors, including coping with cancer, psychological distress, clinical depression, and social support, are not significantly associated with survival time among inoperable patients with NSCLC. Overall, the findings that a specific coping style, 'fighting spirit', and clinical depression

had no significant effect on survival in advanced lung cancer patients should be emphasized because it is commonly believed that a patient's coping with cancer and negative emotions, especially depression, can affect his or her chances of surviving cancer. In addition, because our study confirmed the moderate to high stability of several of the psychosocial factors, we found little convincing evidence that a weak 'fighting spirit' or negative emotions after cancer diagnosis played a clinically relevant role in survival from cancer, even when these findings were stable over relatively long periods of time. Furthermore, our study demonstrates that social support factors do not have an important influence on survival time among advanced lung cancer patients. These findings are consistent with some previous studies and our findings suggest that advanced lung cancer patients need not feel pressured into adopting a specific coping style to cancer or blame themselves for having 'negative emotions and/or depression' after their cancer diagnosis that might affect their survival [37,38]. The present findings may be relevant because the psychological distress experienced by lung cancer patients has been repeatedly reported to be higher than in other cancer patients (see Introduction). Furthermore, this study provides the first findings about clinically diagnosed depression, namely major depression, after a diagnosis of inoperable lung cancer and the subsequent survival time. Although many previous studies have demonstrated a significant association between depression and survival among cancer patients [28,39,40] and patients with other diseases, especially cardiovascular patients [41,42], the current findings are not consistent with the previous findings. This may be partly due to the differences in the subjects and the relatively small sample size (e.g. only six patients suffered from major depression). Further, large studies may be needed to obtain more conclusive findings between clinical depression and survival among lung cancer patients.

Finally, we would like to mention a possible effect of Japanese culture on the findings obtained. In Japan, a diagnosis of cancer is still often considered to be the equivalent of a death sentence, and the disclosure of a cancer diagnosis is not universally practiced [43]. Although the institution at which the present study was conducted is exceptional in that a cancer diagnosis is usually disclosed to the patient, cultural differences in patient-physician communication and the social meaning of a cancer diagnosis may have influenced the psychosocial factors that were investigated and be consequently may be somewhat associated with the present findings. In addition, previous Japanese studies have consistently indicated a somewhat lower prevalence of major depression, ranging between 4 and 7%, among cancer patients,

compared with findings from Western countries [12,44–46]. Thus, the low prevalence of major depression is unlikely to represent a sampling bias, but rather cultural differences—as discussed in our previous study [12,46].

We would like to emphasize that our findings do not imply that dealing with psychosocial issues among cancer patients in clinical oncology setting is unimportant. As many studies have indicated, psychosocial issues not only cause serious suffering [47], but also worsen the quality of life [48], reduces compliance with anticancer treatment [49], can lead to suicide [50], are a psychological burden on the family [51], and prolongs hospitalization [52].

Although it was not the principal purpose of our study, we would like to note that our findings suggest that the serum LDH level could be a useful independent biomedical prognostic factor of the length of survival among patients with advanced NSCLC. LDH is an enzyme that is released into the peripheral blood after cell death. Therefore, the serum LDH level may represent biomedical conditions associated with the length of survival among patients with advanced NSCLC. A rigorous psycho-oncological study investigating the influence of psychosocial factors on survival may be needed to evaluate these biomedical factors as well as psychosocial factors.

Our study also has some weaknesses. First, since only 53.0% (122/230) of the subjects could be included in the analysis, generalizing the results may be problematic, and the sample size of the follow-up group was not very large. Second, the fact that the patients who participated in the study were more likely to have a better PS than those who did not indicate a potential selection bias. Third, as mentioned above, because the number of cases with clinical depression was quite small, the validity of our findings regarding the association between clinical depression and survival may be limited. To overcome these limitations, we are conducting a large-scale cohort study involving more than 2000 subjects to investigate psychosocial factors and survival among lung cancer patients [53]. Since the present study was conducted at one institution, an institutional bias may be another problem. Because current smoking at the time of lung cancer diagnosis could be an independent predictor of survival and a close association between smoking and emotional distress has been documented [54,55], the lack of data on continuous tobacco use after cancer diagnosis and its relationship with emotional distress and survival may be an additional limitation. Finally, because this study focused on advanced NSCLC cancer patients, the results may not be applicable to patients with other types and/or clinical stages of cancer.

Acknowledgements

This study was supported in part by a Grant-in-Aid for Cancer Research from the Japanese Ministry of Labor, Health and Welfare and a Grant-in-Aid for Scientific Research from the Japanese Ministry of Education, Culture, Sports, Science and Technology. The authors wish to thank Yurie Sugihara and Yuko Kojima for their research assistance.

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Self-efficacy, psychological adjustment and decisional-balance regarding decision making for outpatient chemotherapy in Japanese advanced lung cancer

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(Received ■ ■ ■ ■; in final form ■ ■ ■ ■)

Abstract

This study examined the application of the trans-theoretical model (TTM) for readiness for decision-making of outpatient chemotherapy of Japanese advanced lung cancer patients by a cross sectional questionnaire survey. A questionnaire was conducted for 105 Japanese patients diagnosed with advanced lung cancer receiving chemotherapy. We classified them according to the TTM stages including 4 in precontemplation, 42 in contemplation, 22 in preparation, and 35 in action. The valid model ($\chi^2(37) = 42.56$, $p = 0.24$; GFI = 0.93; AGFI = 0.88; CFI = 0.98; RMSEA = 0.04; AIC = 100.56) derived from structural equation modeling (SEM) revealed that stage of outpatient chemotherapy was significantly affected mostly by decisional-balance ($\beta = 0.60$, $p < 0.001$) and partially by time from patient's house to hospital ($\beta = -0.15$, $p < 0.10$), and that decisional-balance was significantly affected by self-efficacy ($\beta = 0.48$, $p < 0.001$) and nausea ($\beta = -0.23$, $p < 0.01$). The findings from our study provided encouraging results for adopting the TTM in decision making for outpatient chemotherapy in Japanese cancer care and several clinical implications were obtained from the results.

Keywords: *Trans-theoretical model, decisional-balance, self-efficacy, outpatient chemotherapy, lung cancer*

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ISSN 0887-0446 print/ISSN 1476-8321 online © 2007 Taylor & Francis
DOI: 10.1080/08870440701623124

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Introduction

Advanced lung cancer carries a poor prognosis and requires treatment with chemotherapy. Recently, improvements in the quality-of-life (QOL) of advanced lung cancer patients has become essential for good cancer treatment and care (Bottomley, Efficace, Thomas, Vanvoorden, & Ahmedzai, 2003; Ishihara et al., 1999). Especially, supportive care in cancer treatment at home is important for their QOL (Sakai, 2002; Tsukagoshi, 2002). In Western countries, outpatient lung cancer treatments are common, but in Japan most patients receive treatment in hospital (Sakai, 2002). One of the reasons for this difference may be the requirement of Japanese national insurance system that chemotherapy is administered in an inpatient setting. Recently, the Ministry of Health decided to allow insurance payments for outpatient chemotherapy for cancer patients (Sakai, 2002). Also, Japanese oncologists have recognized the importance of outpatient chemotherapy for lung cancer to improve the patients' QOL and have started to recommend such outpatient services for their patients (Asai, Minami, Komuta, & Kido, 2000; Chohnabayashi, Uchiyama, Nishimura, & Nasu, 2004; Kawasaki et al., 2003) and several cancer centers have started outpatient clinic centers for cancer patients (Kobayashi & Kobayashi, 2000).

However, patients are still reluctant to make a decision to go home and receive inpatient treatment instead. One reason for reluctance of the patients may be the strong psychological influence on their decision making process. To develop support systems for the patients, clarification of this psychological mechanism is needed. Thus, we tried to apply a framework and a theory from psychology to clarify the patients' decision making process in the transition from inpatient treatment to outpatient treatment.

In health psychology and behavioral medicine, several theories and models have been developed to account for health behavior. Among these, the trans-theoretical model (TTM) (Prochaska & DiClemente, 1983) is useful to explain changes and has been adopted in not only health problem settings such as several studies of smoking cessation (Prochaska & DiClemente, 1984), but also various health behaviors. For example, in the area of cancer medicine, TTM has been applied to examine compliance in health screening for colorectal cancer generic testing (Manne et al., 2002), and mammography adoption (Lauver, Henriques, Settersten, & Bumann, 2003; Rakowski, Fulton, & Feldman, 1993). We believe that application of the TTM to examine patients' behavior and the intention to receive chemotherapy after transitioning from inpatient to outpatient status will be very useful to clarify the psychological factors underlying the patient decision making process for outpatient chemotherapy.

In addition, in the TTM, the function of self-efficacy has an important role in the stage of change, and mediates between the intention for behavioral change and actual behavior (Prochaska & DiClemente, 1984). Several studies have pointed out that self-efficacy has a great impact on psychological adjustment, including the anxiety and depression of advanced cancer patients (Beckham, Burker, Lytle, Feldman, & Costakis, 1997; Hirai et al., 2002;

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Lin, 1998; Merluzzi, Nairn, Hegde, Martinez Sanchez, & Dunn, 2001). It is hypothesized that self-efficacy and psychological adjustment may correspond to the readiness or stage of change for outpatient chemotherapy. Thus, self-efficacy may indicate the possibility to develop psychologically-oriented interventions for patients who would benefit from outpatient chemotherapy.

Thus, this study attempted to examine the readiness for outpatient chemotherapy of advanced lung cancer patients in Japan using TTM. In particular, the attempt was focused on the function of self-efficacy and psychological adjustment in terms of the readiness for the treatment. Finally, we discussed the clinical implications derived from our results.

Methods

Participants

The participants were consecutively recruited from one specialized hospital for chest disease using convenient sampling from March 2003 to July 2003. The sample was composed of 105 Japanese patients diagnosed with advanced metastatic lung cancer, who were inpatients and outpatients receiving chemotherapy. All patients without dementia or delirium were informed of the aim and methods of this study, and their written consent was obtained.

Measures

We developed a questionnaire with a face sheet and four psychological measurements. The face sheet included questions regarding each participant's background, including age, gender, and knowledge and past experience of outpatient chemotherapy.

In a previous preliminary interview study (Hirai, Tokoro, Naka, Ogawara, & Kawahara, 2005) and preliminary analysis (Arai, Hirai, Tokoro, & Naka, 2006), we developed two psychological scales based on TTM: A single item to measure the stage of readiness and a decisional-balance scale for outpatient chemotherapy in lung cancer patients. A single item to evaluate patients' stage of readiness included four alternatives for stage of readiness: *Precontemplation* ("I have no interest in receiving outpatient chemotherapy."), *contemplation* ("I have been thinking that I might want to receive outpatient chemotherapy."), *preparation* ("I am preparing to receive outpatient chemotherapy."), and *action* ("I have already received outpatient chemotherapy."). This item was proved to have content validity through the content analysis of interview data (Hirai et al., 2005). The decisional-balance scale of outpatient chemotherapy is a 20-item scale with two subscales: Pros and cons. The pros consisted of 10 items: *Freedom of movement; comfortable environment; increased relaxation; increased social support; freedom of time; psychological stability; regarding oneself as an ordinary person; fewer time restrictions; decreased concerns; treated as an ordinary person*. The cons also consisted of 10 items: *Worries about instability of illness; dissatisfaction with*

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120 consultation time; worries about insufficient treatment; lack of enough nursing; worries
about side effects; insufficient facilities for treatment; worries about urgent treatment;
125 lack of information from peers; less communication with medical staff; less medical
information. Each subscale of the decisional-balance scale has been shown to have
high reliability (Cronbach alpha = 0.88 for pros and 0.87 for cons) and high
130 structural validity by confirmatory factor analysis ($\chi^2(166) = 223.73$ ($p < 0.001$),
GFI = 0.83, CFI = 0.93, RMSEA = 0.06) for the two-factor structure which was
hypothesized from the results of our interview study (Arai et al., 2006).

The scale of the Self-Efficacy for Advanced Cancer (SEAC) was designed to
135 assess self-efficacy in terms of the illness behavior of advanced cancer patients
(Hirai et al., 2001). It is an 18-item scale with the following three subscales:
Symptom coping efficacy (SCE; e.g., "I can manage insomnia caused by pain");
ADL efficacy (ADE; e.g., "I can enjoy TV or radio programs"); *Affect regulation*
140 *efficacy* (ARE; e.g., "I can maintain a positive attitude"). The scale is formatted
on an 11-point Likert-type scale, ranging from 0 (not at all confident) through
50 (50% confident)–100 (totally confident). Each subscale of SEAC has been
145 shown to have high reliability (Cronbach alpha = 0.73–0.81) and high structural
validity (GFI = 0.93–0.96; Hirai et al., 2001). The scale also succeeded in
clarifying the significant relationships among physical condition, self-efficacy and
psychological adjustment of advanced cancer patients (Hirai et al., 2002).

150 To assess psychological adjustment, we used the Japanese version (Kitamura,
1993) of the Hospital Anxiety and Depression Scale (Zigmond & Snaith, 1983).
The final part of the questionnaire included six items for subjective physical
symptoms (appetite, sleep state, fatigue, dyspnea, feeling of numbness, and pain)
155 and a tangible social support scale (Blake & McKay, 1986).

160 Finally, the physician-in-charge of the participants evaluated their performance
status using the criteria of the Eastern Cooperative Oncology Group performance
status (ECOG PS). ECOG PS is widely used to measure the level of patient
activity using eleven grades (0–4). Also, the physician reported details of each
165 participant's diagnosis, metastasis, chemotherapy regimen, expected prognosis,
and other physical symptoms.

Analyses

170 The descriptive analyses were conducted to summarize the participants'
backgrounds and psychological measurement scores. Those with over
30% missing values on the questionnaire were excluded from the statistical
175 analyses. If one or two scores within the subscales of psychological measurements
were missing, the averaged scores of the series were substituted into a formula
for the total scores of each subscale. Univariate analysis (ANOVA) preliminary
analyzed the factors predicting stage of readiness, and categorical regres-
180 sion analysis was performed using all significant predictor variables ($p < 0.05$).
Because categorical regression analysis proved only one significant and very
strong predictor for stage of readiness, that is, a decisional-balance score,
we performed hierarchical regression analysis using the decisional-balance score

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as a dependent variable. The analysis was repeated to explore multiple relationships among independent variables using significant predictors of the decisional-balance score as dependent variables for each analysis. SEM was performed to confirm the multiple relationships among the significant variables in the results of categorical regression and hierarchical regression analysis. As the categorical regression analysis confirmed a strong linear relationship between stage and decisional-balance, we transformed each participant's ordinal response for stage into numeric scale. To obtain a valid model to account for stage, we compare the Akaike Information Criteria (AIC) index of each model. This measure indicates a better fit when it is smaller. We adopted a model with a parsimonious structure and a smaller AIC index. We conducted all statistical analyses using the SPSS software package (version. 11.0) and AMOS software package (version. 5.0.1).

Results

Characteristics of the participants

The participants consisted of 78 males and 27 females. Table I shows their demographic and diagnostic data including mean age, gender, diagnosis, stage at diagnosis, ECOG PS, distribution of TTM stage for outpatient chemotherapy and mean time from patients' houses to their hospitals. In the distribution of TTM stage, there were four participants in precontemplation, 42 in contemplation, 22 in preparation, and 35 in action. Because of insufficient number ($N=4$) of the participants in precontemplation for multivariate analysis, we excluded their data from the following analyses.

Psychosocial factors associated with the outpatient chemotherapy stage

To explore the differences among patients in the three stages of contemplation, preparation, or action, we reported the mean score of the following independent variables: TTM components, self-efficacy, HADS, physical symptoms and social support (Table II). Participants in the action stage showed a significantly higher score on pros, decisional-balance and the three variables of self-efficacy than participants in contemplation. Participants in contemplation had a significantly higher score on cons and dyspnea than participants in action. For HADS-depression, participants in preparation had the highest score among the three groups.

For TTM components, there were significantly negative correlations between pros and cons ($r=-0.37, p<0.001$), and between cons and decisional-balance ($r=-0.83, p<0.001$), and a significantly positive correlation between pros and decisional-balance ($r=0.82, p<0.001$). In addition, correlations between decisional-balance and both pros and cons were comparatively high ($r=-0.83, p<0.001$; $r=0.82, p<0.001$, respectively). Therefore, we concluded that using these three variables for the multivariate analyses would not be useful and

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Table 1. Demographic characteristics of the participants.

Mean age \pm SD	64.52 \pm 9.40
Gender	
Male/Female	78/27
Diagnosis	105
Lung cancer	55
Ad	23
Sq	1
La	18
Sm	8
Stage at diagnosis	
Stage IA	2
Stage IB	1
Stage IIA	5
Stage IIB	13
Stage IIIA	14
Stage IIIB	66
Stage IV	4
Missing	1
Inpatient/Outpatient	37/68
PS (ECOG)	
0	29
1	69
2	6
Missing	1
TTM Stage for outpatient chemotherapy	
PC	4
C	42
PR	22
A	35
Missing	2
Mean time (minutes) from house to hospital \pm SD	46.19 \pm 32.29 [10-240]

PC: precontemplation, C: contemplation, PR: preparation, A: action.

that only using decisional-balance as a representation of TTM components would be valid.

Categorical regression analysis was preliminary performed on the variables showing a significant relationship with stage differences in ANOVA, and revealed that decisional-balance was the main factor to explain the differences in outpatient chemotherapy stage ($\beta=0.58$, $p<0.001$; $R^2=0.45$). There were no significant effects of other demographic, physical or psychological variables: Affect regulation efficacy ($\beta=-0.03$, *n.s.*), symptom coping efficacy ($\beta=-0.01$, *n.s.*), ADL efficacy ($\beta=0.12$, *n.s.*), HADS-depression ($\beta=0.00$, *n.s.*), and dyspnea ($\beta=-0.11$, *n.s.*). These findings suggested presence of a model in which decisional-balance mediated between psychological and physical variables and outpatient chemotherapy stage. Therefore, in the next step of the analyses, we tried to identify the variables that accounted for the

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Table II. Descriptive data and ANOVA: Mean comparison of outpatient chemotherapy stages.

Measure	Contemplation		Preparation		Action		Total		F(2, 96)	P
	Mean	SD	Mean	SD	Mean	SD	Mean	SD		
TTM components										
Pros	33.67	8.18	37.71	6.00	40.55	6.08	37.00	7.61	9.28	0.000
Cons	39.46	5.95	35.55	4.85	28.06	6.81	34.56	7.84	34.19	0.000
Decisional-balance	-5.79	10.77	2.16	8.59	12.49	9.87	2.44	12.78	31.87	0.000
Self-efficacy										
ARE	59.39	16.05	64.62	22.69	70.33	16.63	64.42	18.37	3.57	0.032
SCE	49.68	24.73	52.50	22.07	62.94	21.33	54.99	23.54	3.34	0.040
ADE	64.22	17.64	68.94	15.32	79.60	17.45	70.71	18.25	7.88	0.001
HADS										
Anxiety	5.81	4.03	6.10	2.68	5.21	2.95	5.66	3.39	0.52	0.594
Depression	6.12	2.72	7.00	2.86	5.16	2.46	5.98	2.73	3.32	0.040
Total	11.93	5.74	13.10	5.01	10.38	4.54	11.64	5.24	1.98	0.144
Physical symptom										
Pain	27.56	23.11	28.18	25.57	24.00	23.91	26.43	23.78	0.29	0.753
Appetite	1.95	0.74	1.91	0.81	1.60	0.69	1.82	0.75	2.35	0.101
Insomnia	1.83	0.66	2.00	0.53	1.66	0.54	1.81	0.60	2.33	0.103
Nausea	1.45	0.71	1.48	0.81	1.18	0.46	1.36	0.66	2.07	0.132
Fatigue	1.95	0.70	1.86	0.89	1.80	0.68	1.88	0.73	0.41	.662
Dyspnea	1.45	0.63	1.23	0.43	1.17	0.38	1.30	0.52	3.18	0.046
Numbness	1.71	0.77	1.45	0.60	1.86	0.81	1.71	0.76	1.94	0.150
Social support										
Tangible assistance	3.81	2.38	4.50	2.79	4.79	3.32	4.31	2.83	1.21	0.304
Performance status										
ECOG PS	0.79	0.61	0.77	0.43	0.79	0.59	0.79	0.56	0.10	0.991

ARE: affect regulation efficacy; SCE: symptom coping efficacy; ADE: ADL efficacy.

variance in the decisional-balance score. Prior to the analysis, preliminary correlation analysis was conducted between decisional-balance and demographic variables (time from house to hospital, stage at diagnosis, expected prognosis, and performance status), physical symptom variables (pain, appetite, insomnia, nausea, fatigue, dyspnea, and numbness), and psychological variables (depression, anxiety and self-efficacy subscales). The results of correlation analysis was represented in Table III. The analysis showed significant correlations, including time from house to hospital ($r = -0.29, p < 0.01$), appetite ($r = -0.25, p < 0.05$), nausea ($r = -0.32, p < 0.01$), dyspnea ($r = -0.21, p < 0.05$), HADS-anxiety ($r = -0.23, p < 0.05$), HADS-depression ($r = -0.23, p < 0.01$), affect regulation efficacy ($r = 0.39, p < 0.001$), symptom coping efficacy ($r = 0.35, p < 0.001$), and ADL efficacy ($r = 0.52, p < 0.001$). Using SEM, we developed a structural model, which regressed the decisional-balance using these nine variables set as predictor variables. First, we assumed two latent variables; one was *psychological adjustment*, which explained anxiety and depression of HADS, and the other was self-efficacy, which explained affect regulation efficacy, symptom coping efficacy, and ADL efficacy, because there were significant

Table III. Intercorrelations among decisional-balance, demographic variables, physical symptom variables, and psychological variables.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
1. Decisional-balance	-																
2. Time from house to hospital	-0.29**	-															
3. Stage at diagnosis	0.01	-0.02	-														
4. Expected prognosis	-0.13	0.07	-0.12	-													
5. Performance status	-0.10	0.20	0.13	-0.30**	-												
6. Pain	-0.14	0.17	0.02	-0.32*	0.25*	-											
7. Appetite	-0.25*	0.13	-0.03	-0.02	0.15	0.31**	-										
8. Insomnia	-0.10	-0.06	-0.03	0.00	0.09	0.25*	0.15	-									
9. Nausea	-0.32**	0.19	-0.09	0.05	-0.02	0.35**	0.31**	0.02	-								
10. Fatigue	-0.15	0.27*	0.03	-0.14	0.12	0.46***	0.47***	0.11	0.40**	-							
11. Dyspnea	-0.21*	0.09	-0.17	0.02	0.15	0.05	0.17	0.23*	0.23*	0.12	-						
12. Numbness	0.10	0.11	0.01	-0.08	0.01	0.17	-0.17	-0.12	0.10	0.08	-0.24*	-					
13. Tangible social support	0.09	-0.14	0.00	-0.04	-0.09	-0.14	-0.01	-0.06	0.02	-0.05	-0.06	-0.02	-				
14. HADS-anxiety	-0.23*	0.12	-0.02	-0.09	0.14	0.40***	0.19	0.21*	0.31**	0.46***	0.32**	0.09	-0.16	-			
15. HADS-depression	-0.23*	0.10	-0.04	-0.10	0.10	0.30*	0.22*	0.08	0.18	0.33**	0.01	0.12	-0.11	0.46***	-		
16. Self-efficacy-ARE	0.39***	-0.15	-0.04	-0.02	-0.05	-0.30**	-0.19	-0.33**	-0.25*	-0.28**	-0.17	0.09	0.23*	-0.42***	-0.42***	-	
17. Self-efficacy-SCE	0.35***	-0.12	-0.06	-0.03	-0.14	-0.18	-0.24*	-0.16	-0.18	-0.16	-0.22*	0.05	0.18	-0.25*	-0.22*	0.53***	-
18. Self-efficacy-ADE	0.52***	-0.24*	0.00	-0.12	-0.10	-0.35***	-0.43***	-0.25*	-0.17	-0.40***	-0.17	0.10	0.29*	-0.47***	-0.43***	0.72***	0.59***

* $p < 0.05$. ** $p < 0.01$. *** $p < 0.001$. ADE: ADL efficacy; SCE: symptom coping efficacy; ARE: affect regulation efficacy.

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correlation among these variables. We set environmental and physical symptom variables; time from house to hospital, appetite, nausea, and dyspnea as independent variables in the model, and the latent variables; psychological adjustment and self-efficacy as mediating variables between environmental and physical variables and decisional-balance. Also, we draw a path from self-efficacy to psychological adjustment because our previous research indicated that there was significant relationship between them (Hirai et al., 2002). As we removed no significant paths from full path model (AIC=94.69), which contained all regressed paths to decisional-balance, until the AIC index of model became the least score (AIC = 88.53) among the models, we obtained the final model as indicated in Figure 1. The model excellently fit the data (χ^2 (26) = 36.53, $p = 0.16$; GFI = 0.93; AGFI = 0.88; CFI = 0.97; RMSEA = 0.05; AIC = 88.53) and accounted for 31% of total variance in decisional-balance by self-efficacy ($\beta = 0.48$, $p < 0.001$) and nausea ($\beta = -0.23$, $p < 0.01$).

Finally, we added a variable, the stage for outpatient chemotherapy, into the model in Figure 1. As we also tested the AIC index from the full path model (AIC = 105.85), which contained all regressed paths to stage, to the model with the least AIC index (AIC = 100.56), the final model represented in Figure 2, was obtained. Fit indices for this model were excellent: χ^2 (37) = 42.56; $p = 0.24$; GFI = 0.93; AGFI = 0.88; CFI = 0.98; RMSEA = 0.04; AIC = 100.56. Overall, the final model accounted for 40% of the variance in stage for outpatient chemotherapy by decisional balance ($\beta = 0.60$, $p < 0.001$) and time from house to hospital ($\beta = -0.15$, $p < 0.10$).

Discussion

The findings from our study provided encouragement for adopting the TTM in the decision-making for outpatient chemotherapy in Japanese cancer care,

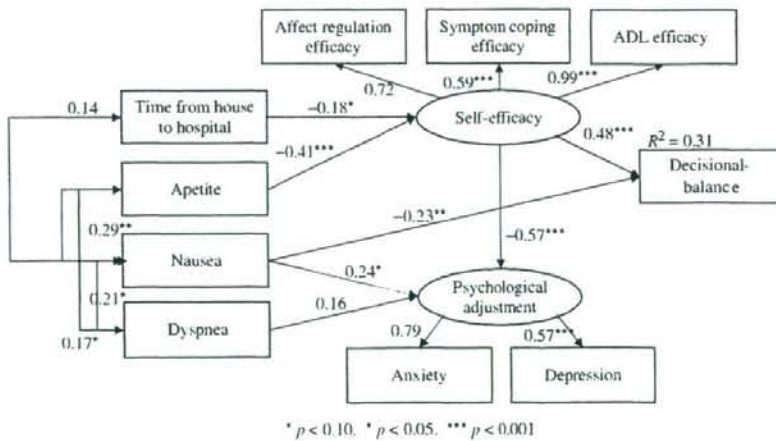


Figure 1. Structural model for decisional-balance of outpatient chemotherapy.

Caregiving Consequences Inventory: a measure for evaluating caregiving consequences from the bereaved family member's perspective

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Abstract

Objective: The aims of this study were to validate an instrument for measuring bereaved family members' perceptions of caregiving consequences and to examine the association between caregiving consequences and psychological distress.

Methods: Cross-sectional questionnaires were administered to family members of patients who had died in regional cancer centers. We measured the Caregiving Consequences Inventory (CCI), respondent's optimism, overall reward scale, and psychological distress and collected background data. A retest was conducted.

Results: Bereaved families from two regional cancer centers were surveyed ($N = 189$ and 109 ; effective response rate, 57 and 80%). By exploratory and confirmatory factor analyses, we identified four perceived reward domains: 'mastery', 'appreciation for others', 'meaning in life', and 'reprioritization', and one perceived burden domain. Although the four reward domains were highly correlated with each other ($0.47 < r < 0.69$), the 4-domain model was superior. The respondents with less education, strong faith, and less optimism reported fewer perceived rewards, thus demonstrating known group validity. In addition, perceived reward had little or no correlation with psychological distress. The psychometric properties of this scale were good ($\alpha = 0.78-0.93$, ICC = 0.60-0.73) and construct validity was supported (GFI = 0.929; AGFI = 0.819; CFI = 0.749; RMSEA = 0.097).

Conclusions: The CCI is valid for measuring caregiving consequences from the bereaved family member's perspective in Japan. Furthermore, it is important to use perceived rewards and burdens as a measure of caregiving consequences for improving the quality of the caregiving and bereavement experience.

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Keywords: caregiving; palliative care; neoplasms; measures; reward; burden

Received: 15 December 2007
Revised: 30 July 2008
Accepted: 3 August 2008

Introduction

The World Health Organization concept of palliative care includes attention to the health and well-being of the family members caring for a patient, and it proposes a support system to help caregivers cope during the patient's illness and their own bereavement [1]. Research has shown that caring for severely ill patients can have a negative impact on the mental, physical, and financial well-being of the caregivers [2-5]. In addition, the caregiver's

burden is associated with family dissatisfaction and regret in received care [6], depression in family members [7,8], and caregiver mortality [9,10] in the course of caregiving and bereavement. Thus, palliative care specialists and researchers have tried to help reduce the caregiver's burden [11-15].

While past research has clearly documented the negative emotions experienced during caregiving and bereavement, recent research has investigated positive consequences of caregiving [16]. Approximately 60-70% of caregivers have reported

that they could recognize positive aspects of the experience [17–19], and psycho-educational interventions have had long-term positive effects on caregiving consequences [20,21]. Although several positive outcomes of caregiving such as appreciation, gratification, mastery, finding meaning and purpose in life, reprioritization, personal growth, and satisfaction [22–26] have been explored, the operational definitions of words used by researchers vary [16] and there is no consensus on what constitutes positive caregiving outcomes.

In Japan, cancer is the leading cause of death. Although enhancement of palliative care for Japanese cancer patients and family caregivers is a priority in Japan, we found only a few studies that investigated in detail caregiving for severely ill cancer patients. To deliver appropriate support for family caregivers, it is important to evaluate both positive and negative caregiving outcomes. There are a few scales that evaluate both positive and negative caregiving outcomes [27,28]. However, in these scales, various positive aspects are measured in 1 domain only, and it is difficult to understand the positive aspects of caregiving in detail. Moreover, surveys of families of patients at the end of life are not culturally appropriate in Japan. Thus, for considering how to provide care to the families, it is necessary to assess caregiving consequences, that is, the positive and negative experiences of the caregivers from the bereaved family's viewpoint. It is difficult to use the scale with many items (more than 20 items) for vulnerable bereaved families in Japan. Today, however, there are a few brief scales.

The aim of this study was to develop a brief measure for evaluating caregiving consequences from the bereaved family member's perspective and to measure the validity and reliability of this new measure in Japan.

Methods

This survey was made up of two cross-sectional anonymous mailed surveys of the bereaved family members of cancer patients in two regional cancer centers in Ibaraki Prefecture (Part 1) and Shizuoka Prefecture (Part 2). Both centers have general wards and inpatient palliative care units (PCU).

Measurements

Caregiving Consequences Inventory (CCI)

To evaluate the consequences of caring for incurable cancer patients from the bereaved family's perspective, we pooled items found through a systematic literature review of studies that described the positive aspects of caregiving [22–25,29–31], caregiver burden [2–5], caregiving-related concepts [16,26,32–38], stress-related growth [39–41], and discussions about the similar-

ity of the concepts. Reviewers were a research nurse specializing in palliative care, a palliative care specialist, and a researcher specializing in clinical psychology. Then, we hypothesized a factor structure prior to psychometric testing of 5 domains of perceived rewards: personal growth, mastery, appreciation for others, meaning in life, and reprioritization, and 1 domain of perceived burden. In Japan and overseas, both a Caregiving Burden Scale with a clear domain structure [42,43] and one without a clear structure [44,45] are used. However, we used 1 domain for the caregiving burden in this survey for the following reasons: (1) the size of the contribution of the first factor is very large compared with the second factor and (2) the caregiving burden in Japan can be assumed to be included in 1 domain [46,47]. We also discussed the content validity for the items using the following selection criteria: (1) easily understood and completed, (2) potentially applicable to both caregiving and bereavement, (3) comprising hypothesized dimensions, and (4) comprising three or more items for each domain. We then selected 19 items as perceived reward domains and 5 items as perceived burden domains. All of the authors were in agreement on these items and factors. This process ensured the content validity of the initial 24-item version of the CCI (available from the authors). These items were rated using a 7-point Likert scale (1: absolutely disagree, 2: disagree, 3: somewhat disagree, 4: unsure, 5: somewhat agree, 6: agree, 7: absolutely agree). We used the initial 24-item version in Part 1 of the survey and the 16-item shortened version in Part 2.

Overall perceived rewards

We asked about overall perceived rewards with the statement: 'It was a good experience for me to care for my family member' using a 7-point Likert scale (1: absolutely disagree, 2: disagree, 3: somewhat disagree, 4: unsure, 5: somewhat agree, 6: agree, 7: absolutely agree). We used this scale to examine the concurrent validity of the CCI in Part 2 of the survey. We did not have scales to examine details of positive aspects of caregiving consequences when the survey was conducted. We therefore used a single item to measure concurrent validity, the best method in such a situation [48].

The Life Orientation Test—Revised (LOT-R)

Research has shown that optimism is associated with positive aspects of difficult situations [18,49]. We hypothesized that the perceived reward domain score is positively correlated with optimism of the respondents. The LOT-R is a 10-item (six target items and four fillers) self-report scale measuring expectations about positive outcomes in general, using a 5-point scale from 0 (strongly disagree) to 4 (strongly agree) [49]. The validity and reliability of

the Japanese version have been confirmed, and Sakamoto proposed a two-factor model consisting of optimism and pessimism [50]. Responses are scored from 0–12 with higher scores on the three optimism items representing greater dispositional optimism, while higher scores on the three pessimism items represent greater dispositional pessimism. We used this scale to examine the known group validity of the CCI in Part 1 of the survey.

The General Health Questionnaire-12-item version (GHQ-12)

The GHQ-12 is a screening instrument covering a range of psychiatric symptoms (e.g. anxiety and depression) as well as somatic symptoms and social dysfunction [51]. We used the GHQ-12 to measure the degree of psychological distress of the respondents and to examine the discriminate validity of the CCI in Part 2 of the survey.

Background data of caregivers and patients

The patient's age, sex, and number of hospital days, time since patient's death, and care settings were extracted from medical databases. The caregiver's background data included the bereaved family member's age, sex, relationship with the patient, and frequency of attending the patient.

In Part 1, we also asked the respondents about health status during the caregiving period, presence of other caregivers, whether the caregiver lived with the patient, and caregiver's faith, education, and household income during the caregiving period. Research has shown that caregivers with less education and strong faith reported fewer perceived rewards [52,53]. Thus, we used these data to examine the known group validity of the CCI.

Participants and procedures

To find potential participants for Part 1 of the survey, we identified from medical records bereaved family members of patients who died from lung or gastrointestinal cancer from September 2004–February 2006 on the general ward in a regional health center in Ibaraki Prefecture and patients who died from all forms of cancer in PCUs in the same regional health center during the same period. We mailed questionnaires to potential respondents in October 2006 and a reminder was sent in November 2006 to those who did not respond. The respondents were asked to report the level of agreement on the initial 24-item CCI and LOT-R and to supply background data. To examine test–retest reliability, we sent the same questionnaire one month later.

For Part 2 of the survey, we identified from medical records bereaved family members of patients who died from April 2005–April 2006 in PCUs of regional cancer centers in Shizuoka

Prefecture. We mailed questionnaires to potential respondents in March 2007 and a reminder was sent in April 2007 to those who did not respond. The respondents were asked to report their level of agreement with the final 16 items of the shortened version of the CCI, their overall perceived rewards, responses to the GHQ-12, and background data.

The inclusion criteria were the same in both surveys and were as follows: (1) patient was aged 20 years or more and (2) patient was hospitalized at least 3 days. The exclusion criteria were the same in both surveys: (1) participant was recruited for another 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, (4) participant was incapable of replying to a self-reported questionnaire, and (5) participant was not aware of the diagnosis of malignancy.

Ethical consideration

The protocols were approved by the institutional review board of each institute. In both Part 1 and Part 2, 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.

Statistical analyses

Scale development

For item reduction, we first deleted items with data missing for 20% or more of the respondents, or highly skewed distributions of the ratings defined as 'mean \pm standard deviation' beyond the scope of the variable. We then used exploratory factor analysis using the maximum likelihood method [54] with a promax rotation for perceived reward domains and perceived burden domains, separately. According to the results of the exploratory factor analysis, attributes with factor loadings less than 0.3 (standardized regression coefficient) were deleted. Among several models tested, we adopted the model that showed sufficient fitness to the factor structure based on the hypothesized concepts and clinical validity based on full agreement of the authors. The items that were finally adopted for the CCI are described in the appendix. The domain score was calculated by summing the items in each domain. The total reward score was calculated by summing the 12 items in all perceived reward domains, although we did not provide the CCI total score, which was calculated by summing the 16 items, including 12 perceived reward items and four burden items.

Scale validation

Validity: To examine concurrent validity, we calculated the Pearson's correlation coefficients between each domain of the CCI and one item overall for perceived rewards using data from Part 2. In addition, to examine construct validity of the final 16 items of the CCI, we calculated the Pearson's correlation coefficients between each domain score of the CCI using data from Part 1, and conducted a confirmatory factor analysis using data from Parts 1 and 2, separately. Known group validity was examined using a *t* test to compare the reward domain scores of respondents who had more faith compared with those with less faith, scores of respondents who had more education compared with those with less education, and scores of respondents who were more optimistic compared with those who were less optimistic.

Faith responses were grouped into a group with less faith (1: none at all and 2: slightly strong) and a group with more faith (3: moderately strong and 4: very strong). In addition, responses about education level were grouped into a group with less education (1: finished junior high school and 2: finished high school) and a group with more education (3: junior college graduate and 4: college graduate). As for optimism and set the threshold value for optimism was established at 6/7.

In addition, to examine discriminant validity, we calculated the Pearson's correlation coefficients between each domain score of the CCI and psychological distress. We used GHQ scoring (0-0-1-1), and set the threshold for psychological distress at 2/3 [55]. We divided the score into binary variables whether the score exceeded a cutoff value or not, and used it as a dependent variable.

Reliability: To examine the reliability of the CCI, we calculated Cronbach's α coefficients (Cronbach's α) and intra-class correlation coefficients (ICC) for test-retest reliability using data for Part 1 of the survey.

All analyses were performed using the statistical package SAS version 9.1 (SAS Institute) and AMOS version 7.0 (SPSS institute). The significance level was set at $P < 0.05$ (two-tailed).

Results

Of 344 and 160 questionnaires sent to bereaved family members in Part 1 and Part 2, respectively, 11 and 23 were undeliverable, and 215 and 121 were returned. Among these, 23 and 12 individuals refused to participate, and 3 and 0 were excluded due to missing data. Thus, 189 and 109 responses were analyzed (effective response rates, 57 and 80%, respectively).

As for follow-up of Part 1, of 175 questionnaires sent to bereaved families who responded during the study period, nine individuals refused to partici-

pate, and two responses were excluded due to missing data. Finally, 112 responses were analyzed (effective response rate, 64%). Table 1 summarizes the background of the respondents.

Item reduction

In accordance with the above-mentioned item reduction procedure, we initially excluded one item

Table 1. Backgrounds of respondents

	Part 1 (N = 189)		Part 2 (N = 109)	
	n	%	n	%
Patients				
Age, y (mean \pm SD)	69 \pm 12		73 \pm 11	
Sex				
Male	108	57	47	43
Female	81	43	62	57
Hospital days (mean \pm SD)	41 \pm 37		56 \pm 74	
Care setting				
General ward	55	29	0	0
Palliative care unit	134	71	109	100
Bereaved family members				
Age, y (mean \pm SD)	57 \pm 12		60 \pm 12	
Sex				
Male	63	33	42	39
Female	122	65	64	59
Time since patient's death: months (mean \pm SD/range)	15 \pm 5 (7-25)		17 \pm 4 (11-24)	
Relationship				
Spouse	87	46	47	43
Child	64	34	42	39
Child-in-law	20	11	8	7
Other	15	9	10	10
Health status				
Good	48	25	—	—
Moderate	106	56	—	—
Fair	28	15	—	—
Poor	5	3	—	—
Presence of other caregivers				
Present	131	69	—	—
Absent	54	29	—	—
Living status				
Living together	157	83	—	—
Not living together	30	16	—	—
Religiousness				
Much	14	7	—	—
Moderate	34	18	—	—
Fair	46	24	—	—
None	85	45	—	—
Education				
Junior high school	34	18	—	—
High school	82	43	—	—
College	40	21	—	—
University	31	16	—	—
Household income (thousand yen)				
000-249 (-2500\$)	31	16	—	—
250-499 (2500-4990\$)	74	39	—	—
500-749 (5000-7490\$)	37	20	—	—
750-999 (7500-9990\$)	21	11	—	—
1000- (10000\$-)	16	8	—	—

Several total percents do not equal 100% due to missing values.

Caregiving consequence inventory

Table 2. Exploratory factor analysis of Caregiving Consequence Inventory

	Standardized regression coefficients				Communality	
	F1	F2	F3	F4		
<i>Perceived reward domain</i>						
1 Mastery (mean = 4.9, SD = 1.2)						
Q1	I feel confident enough to manage future life changes	0.91	0.05	-0.06	0.04	0.86
Q2	I have learned to cope better with my life	0.83	-0.10	0.05	0.18	0.85
Q3	I came to accept some of the changes in my life	0.75	0.11	0.14	-0.18	0.64
2 Appreciation for others (mean = 5.5, SD = 1.0)						
Q4	I came to have more appreciation for others	-0.04	0.96	-0.03	0.04	0.90
Q5	I became more aware of love from other people	0.06	0.84	-0.01	0.07	0.81
Q6	I came to place greater value on relationships	0.06	0.71	0.10	-0.06	0.58
3 Meaning in life (mean = 4.9, SD = 1.2)						
Q7	I came to find purpose and sense of meaning in my life	-0.04	0.04	1.00	-0.06	0.94
Q8	I have a better outlook on my life	0.19	0.00	0.64	0.07	0.66
Q9	I came to believe that there was a meaning in life no matter what happened	0.19	-0.05	0.63	0.15	0.69
4 Reprioritization (mean = 5.6, SD = 1.0)						
Q10	I came to understand of the brevity of life and appreciate each day	-0.02	-0.01	0.01	0.99	0.96
Q11	I came to notice what is really important in my life	0.21	0.17	0.09	0.50	0.66
Q12	I have learned the importance of being alive	-0.09	0.14	0.42	0.43	0.61
<i>Perceived burden domain</i>						
Burden (mean = 3.7, SD = 1.6)						
Q13	I felt a physical burden			0.96		0.58
Q14	I sacrificed my own time and schedule			0.76		0.92
Q15	I felt a mental burden			0.67		0.44
Q16	I felt a financial burden			0.33		0.11

Table 3. Concurrent validity of Caregiving Consequence Inventory

	Overall perceived
<i>Perceived reward domains</i>	
Mastery	0.37***
Appreciation for others	0.30***
Meaning in life	0.39***
Reprioritization	0.43***
Total reward score	0.44***

Figures are Pearson's correlation coefficients. * $P < 0.05$, ** $P < 0.01$, *** $P < 0.001$.

due to skewed responses from the initial CCI. According to the results of the exploratory factor analysis, 12 items for perceived rewards and 4 items for perceived burden were selected. The following 4 domains were extracted as perceived rewards: (1) mastery, (2) appreciation for others, (3) meaning in life, and (4) reprioritization. The result of the exploratory factor analysis of the CCI is shown in Table 2.

Scale validation

Validity

Table 3 shows the concurrent validity. The correlation of each reward domain of the

CCI and the one-item overall perceived reward was moderate and ranged from $r = 0.30$ to 0.43.

Table 4 shows the known group validity and demonstrates significant differences in each reward domain of the CCI according to the hypothesized respondent's characteristics (i.e. the respondent's faith, education, and optimism).

Figure 1 shows the result of confirmatory factor analysis using data from Part 1 of the survey. This solution has the most interpretable factors and showed sufficient fitness to the factor structure, consistency with the hypothesized concepts, and clinical validity. Although we hypothesized a model with five perceived rewards including a personal growth domain at first, exploratory factor analysis revealed that the three items we hypothesized as personal growth were due to an improper solution and no convergence could be attained. Therefore, we adopted 12 items for four perceived reward domains and 4 items for the burden domain. The fit indices for this final model were acceptable (χ^2 262.333 [df = 99], $P < 0.001$; GFI = 0.919; AGFI = 0.848; CFI = 0.792; RMSEA = 0.094) (see Figure 1). The confirmatory factor analysis using Part 2 data reproduced acceptable fit indices with one correlated error term (χ^2 191.6 [df = 98], $P < 0.001$; GFI = 0.929; AGFI = 0.819; CFI = 0.749; RMSEA = 0.097) (see Figure 2).