Fig. 2. Changes in the DT.

weeks, and the change in a DT was strongly associated with changes in physical symptoms. This result suggests that chemotherapy-related physical symptoms may highly influence the DT and result in rapid changes within several weeks in the outpatient chemotherapy setting. Future study is required to assess the usefulness of the DT as a clinical tool to identify patients with psychiatric comorbidity. Modifying the procedure, such as two-point follow-up, or encouraging symptom control to be

maximized before rating the DT, may be necessary. In the meantime, clinicians should note that a high score in the DT is not simply the indicator of psychiatric comorbidity. DT often indicates the need of palliating co-existing physical symptoms.

Age and gender differences in the symptoms of cancer patients are a focus of some researches.[39-45] Consistent with previous findings from a systematic review of symptom prevalence,[44] higher pain intensity was significantly associated with younger age. This result indicates that younger patients need special attention in terms of pain management and active monitoring of pain. We also observed gender differences in some symptoms: male patients reported a higher intensity of fatigue, dyspnea, appetite loss, and somnolence, in addition to a higher dose of opioids, after adjustment for age and primary tumor sites. This result is not consistent with a large-scale study of patients receiving no anticancer treatments that revealed a gender difference in the prevalence of nausea.[44,45] Potential interpretations of these differences include: 1) different measurement methods (i.e., symptom intensity vs. frequency); 2) different treatment settings (receiving chemotherapy in the outpatient setting vs. palliative phase); and 3) analyses with or without adjustment for other factors. To determine the effects of age and gender on symptom intensity in this population, more pooled data from this setting is necessary.

This was a descriptive study of clinical experience and thus had considerable limitations. First, as the patients were a heterogeneous sample of primary tumor sites, stages, and

Table 4
Comparison of Patients with a DT of 6 or More and Below 6 at Follow-up

	Patients with DT of 6 or More at Follow-up ($n = 50$)	Patients with DT below 6 at Follow-up ($n = 115$)	P Value
Age	63 ± 9.6	63 ± 11	0.26
Sex (male)	56% ($n = 28$)	44% ($n = 51$)	0.17
At initial assessment			
Pain	3.2 ± 2.6	2.8 ± 2.8	0.63
Dyspnea	2.3 ± 2.6	1.8 ± 2.5	0.49
Nausea	2.1 ± 2.8	2.2 ± 3.0	0.11
Appetite loss	3.4 ± 3.1	3.4 ± 3.3	0.38
Somnolence	3.0 ± 2.5	2.5 ± 2.4	0.89
Fatigue	4.6 ± 3.0	3.5 ± 2.8	0.56
Constipation	2.4 ± 2.6	2.9 ± 3.2	0.027
Numbness	2.8 ± 3.0	1.8 ± 2.7	0.16
DT	7.4 ± 1.2	7.6 ± 1.3	0.15
At the follow-up			
Pain	3.5 ± 2.7	1.5 ± 1.8	0.001
Dyspnea	3.1 ± 2.8	1.1 ± 1.8	<0.001
Nausea	2.2 ± 2.7	0.48 ± 1.0	<0.001
Appetite loss	3.7 ± 3.0	1.1 ± 1.8	<0.001
Somnolence	3.9 ± 2.7	1.3 ± 1.6	<0.001
Fatigue	5.0 ± 3.0	1.9 ± 2.3	0.005
Constipation	3.1 ± 2.9	1.4 ± 2.3	<0.001
Numbness	3.0 ± 3.1	1.0 ± 1.7	<0.001

Analyses were performed on patients who had a DT score of 6 or more at any time in this study period ($n = 165$).

chemotherapy regimens, the results cannot be automatically generalized to specific target populations. We believe that this is not a fatal flaw of this study, but rather can be a strength, because we need to develop a useful system for heterogeneous outpatients receiving chemotherapy. Second, this was a single-institution study. We believe, however, that the results are generalizable to other institutions, as our hospital is a typical general hospital functioning as a regional cancer center. Third, we adopted the single-item DT to increase patients' compliance. The combined use of the DT and impact thermometer (i.e., the degree of interference to daily activity) might decrease the influence of physical symptoms. Finally, we did not analyze the effects of chemotherapy cycle of each regimen on symptom intensity, and this should be explored in a future study.

In conclusion, frequent symptoms of cancer outpatients receiving chemotherapy are categorized as: 1) psychosocial issues (insomnia, psychological distress, decision-making support); 2) nutrition-gastrointestinal issues (oral problems, appetite loss, nausea); 3) fatigue; and 4) pain, dyspnea, and numbness. Developing a systematic intervention program targeting these four areas is urgently required. The DT might be an effective tool to monitor psychological distress but can be highly influenced by coexisting physical symptoms. Future studies are required to determine the intervention effects in the above four areas and to develop more appropriate procedure to identify patients with psychiatric comorbidity.

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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: caregiver; palliative care; neoplasms; measures; reward; burden

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 factor42 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 discriminate 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 oneitem

Table 1. Backgrounds of respondents

	Part 1(N = 189)		Part 2(N = 109)	
	n	%	n	%
Patients				
Age, y (mean±SD)	69±12		73±11	
Sex				
Male	108	57	47	43
Female	81	43	62	57
Hospital days (mean±SD)	41±37		56+/74	
Care setting				
General ward	55	29	0	0
Palliative care unit	134	71	109	100
Bereaved family members				
Age, y (mean±SD)	57±12		60±12	
Sex				
Male	63	33	42	39
Female	122	65	64	59
Time since patient's death: months (mean±SD/range)	15±5(7–25)		17±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.

Table 2. Exploratory factor analysis of Caregiving Consequence Inventory

		Standardized regression coefficients				Communality
		FI	F2	F3	F4	
Perceived reward domain						
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
Perceived burden domain						
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

	Oveall perceived
Perceived reward domains	
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).

Table 4. Known-group validity of Caregiving Consequence Inventory

	Faith				P-value	Education				P-value	Optimism				P-value
	Less faith		More faith			Less educated		More educated			Less optimistic		More optimistic		
	Means	SD	Means	SD		Means	SD	Means	SD		Means	SD	Means	SD	
Perceived reward domains															
Mastery	4.8	1.2	5.2	1.0	0.02*	5.1	1.1	4.6	1.3	0.01*	4.8	1.1	5.2	1.2	0.03*
Appreciation for others	5.5	1.1	5.6	1.0	0.63	5.6	1.0	5.4	1.2	0.32	5.5	1.0	5.7	1.1	0.15
Meaning in life	4.8	1.2	5.4	0.9	<0.001***	5.2	1.0	4.6	1.3	0.001**	4.9	1.1	5.1	1.3	0.13
Reprioritization	5.4	1.1	5.8	0.8	0.03*	5.7	0.9	5.4	1.2	0.06	5.4	1.0	5.9	1.1	0.003**
Total reward score	5.1	1.0	5.5	0.7	0.01*	5.4	0.8	5.0	1.0	0.01*	5.1	0.9	5.5	1.0	0.03*

*$P < 0.05$, **$P < 0.01$, ***$P < 0.001$.
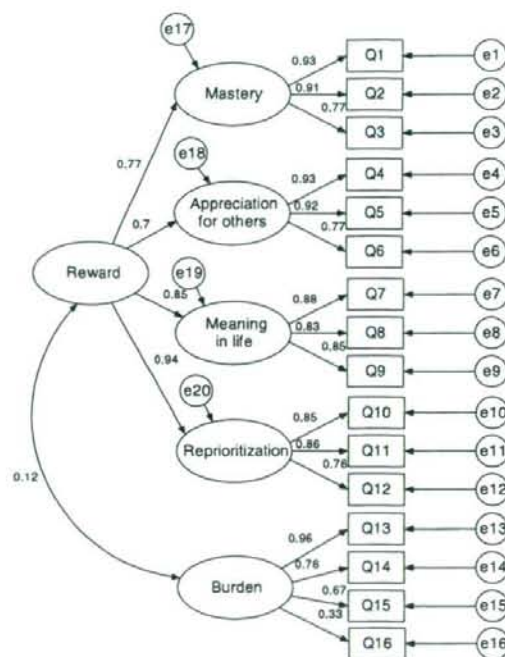
Figure 1. Confirmatory factor analysis of Caregiving Consequence Inventory (Part 1). $\chi^2$262.333 (DF = 99), $P < 0.001$; GFI = 0.919; AGFI = 0.848; CFI = 0.792; RMSEA = 0.094

The four reward domain scores were highly correlated with each other ($0.47 < r < 0.69$) (Table 5). We tested the factor structure of reward further by conducting confirmatory factory analyses, comparing the 4-reward domain and 1-reward domain approaches. The analysis revealed that the 4-reward domain model fit the data significantly better than the 1-reward domain model (χ^2 699.4 [df = 103], $P < 0.001$; GFI = 0.692; AGFI = 0.652; CFI = 0.541; RMSEA = 0.186).

Table 6 shows the known group validity and shows that no significant correlation exists between each domain score and psychological distress, except for a slight correlation with mastery ($r = -0.19$, $P = 0.05$) and burden ($r = 0.24$, $P = 0.01$).

Reliability

Table 7 shows the internal consistency and test–retest reliability. Cronbach's α ranged from 0.78 to 0.93. The Cronbach's α coefficient of the total reward domain was 0.93 and of the burden domain was 0.78. The ICC ranged from 0.60 to 0.73. The ICC of the total reward domain was 0.73 and of the burden domain was 0.60.
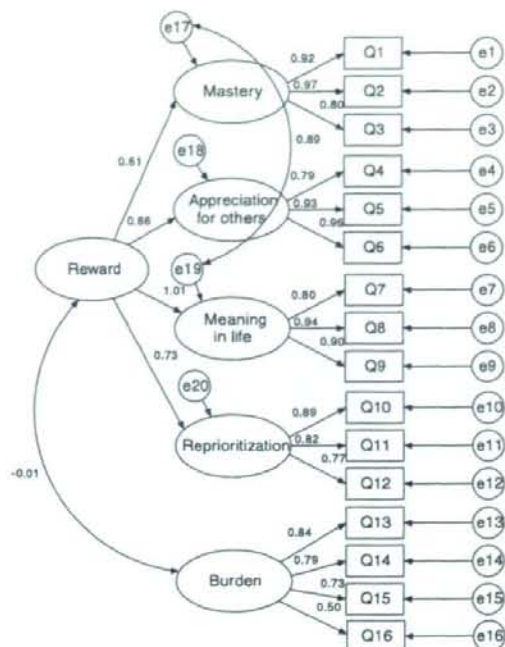
Figure 2. Confirmatory factor analysis of Caregiving Consequence Inventory (Part 2). χ^2 191.6 (DF = 98), $P < 0.001$; GFI = 0.929; AGFI = 0.819; CFI = 0.749; RMSEA = 0.097

Table 5. The association with each other domain score of CCI

	Mastery	Appreciation for others	Meaning in life	Reprioritization
Mastery	1.00			
Appreciation for others	0.47***	1.00		
Meaning in life	0.63***	0.49***	1.00	
Reprioritization	0.60***	0.60***	0.69***	1.00
Burden	0.07	0.06	0.12	0.07

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

Table 6. The association between caregiving consequence and psychological distress

	Psychological distress
Perceived reward domains	
Mastery	−0.19*
Appreciation for others	0.11
Meaning in life	−0.13
Reprioritization	−0.01
Total reward score	−0.07
Perceived burden domain	
Burden	0.24*

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

Discussion

The most important result of this study was the development of an instrument to measure the bereaved family's perceptions about the caregiving experience in Japan. The instrument showed good internal consistency and test–retest reliability, and known group validity was also consistent with a previous study [52,53]. The CCI is 16 items and takes less than 10 min to complete. Plain terms are used for these items, so the deficit rate is low 2% or less. Thus, we believe that this scale can assess caregiving consequences with few demands placed on the bereaved family.

Exploratory factor analysis and confirmatory factor analysis revealed 5 domains consisting of 4 sub-domains of perceived rewards and 1 domain of perceived burden: mastery, appreciation for others, meaning in life, reprioritization, and burden. The themes of the domains are consistent with our prior hypothesized concepts.

Items selected for the 'mastery' domain represented the extent to which the respondent felt in control over his or her life [35,36,56]. Although the operationalization of 'meaning' varied widely across studies and sometimes represented overall

Table 7. Reliability of Caregiving Consequence Inventory

	α	ICC
Perceived reward domains		
Mastery	0.90	0.73
Appreciation for others	0.90	0.60
Meaning in life	0.89	0.62
Reprioritization	0.86	0.67
Total reward score	0.93	0.73
Perceived burden domain		
Burden	0.78	0.60

α, Cronbach's alpha coefficient; ICC, intra-class correlation coefficient.

positive aspects of caregiving [34,57], items selected for 'meaning' in life domains assessed the sense of purpose in life and task [57]. The 'appreciation for others' domain included items about gratitude for relationships and compassion [52], and the 'reprioritization' domain assessed changes in values and attitudes about living life to the fullest [23,52]. These 4 reward domains are similar to those identified in other studies of post-traumatic growth [39,40], and the burden domain included the items identified important for assessing caregiver burden [2,3,12,14]. Thus, content validity is assured.

It was not surprising that the 4 reward domain scores were highly correlated with each other because a sense of mastery may occur through the development of new capabilities and finding a sense of meaning or purpose [32]. In addition, caregivers described their deeper appreciation for relationships for one of the changes in values [31]. On examining concurrent validity, each reward domain of the CCI and overall perceived rewards were only moderately correlated, and the comparisons between the 4-domain and 1-domain models of perceived rewards revealed the superiority of the 4-domain model. We thus believe that a comprehensive assessment of rewards by one overall item is difficult and evaluation of every domain is recommended.

As for discriminate validity, almost none of the reward domains correlated with psychological distress. Only mastery and burden showed slight correlation with psychological distress, however these correlations were very weak. Therefore, we believe that mastery and burden were not clinically correlated with psychological distress.

This means that the caregiver considered reward to be an entity distinct from psychological distress, and it is important to use perceived reward as a measure for evaluation of caregiving consequences, as well as the caregiving burden, for improving the quality of the caregiving and bereavement experience.

Although the domains of the CCI demonstrated sufficient internal consistency, reliability measured by ICC was of moderate value [58]. Possible reasons for the moderate reliability are (1) the test–retest period was longer than 1 month and (2)

the family member's assessment of the CCI may have changed over time. However, the sufficient internal consistency as a measure of reliability for a cross-sectional study is appreciated; therefore, these moderate ICCs are not considered critical limitations of the CCI.

Limitations and future perspectives

The limitations of this study are as follows: first, the response rate in Part 1 of the survey was 57%. We think that this was low because the response rate of the bereaved families receiving care on the general wards was low (47% on general wards vs 62% in PCU). We believe, however, that the effect on this study was not crucial because (1) the objective was to validate a scale, not to survey actual conditions and (2) comparing the backgrounds of respondents and non-respondents revealed no differences in age, gender, the length of patient's hospital stay, or time since patient's death. Second, we identified the bereaved family members of patients who died from lung or gastrointestinal cancer on the general wards in Part 1 of the survey. We believe, however, that the effect on this study was not crucial because (1) the proportion of deceased patients on the general wards who died from other types of cancers was only 12% (23/188) in Part 1 and (2) we identified the bereaved family members of patients who died of all types of cancer on the PCU in Parts 1 and 2 of the survey. Third, we were unable to examine concurrent validity sufficiently in this study because we did not have scales to examine the details of positive aspects of caregiving consequences when this survey was conducted. Fourth, we set only one correlation between errors in the confirmatory factor analysis in Part 2 because of insufficient sample size. However, we believe this is not a fatal flaw because the fit indices for this final model in Part 1 were acceptable. We are going to perform further confirmation with a larger sample size in the next step. Fifth, this validation was executed in Japan, a culturally and ethnically homogeneous country. It is necessary to examine whether the structure of CCI can be reproduced in different cultures.

In the future, we would like to conduct a national survey on the actual positive and negative aspects of caregiving consequences in Japan. To decide the focus of the intervention, it is necessary to clarify factors related to positive and negative experience, and to explore the mechanisms that maintain and increase positive experiences, as well as those that decrease negative experiences. This CCI provides a good base for further exploration of these mechanisms. We also would like to conduct a prospective survey to clarify factors related to the change of perceived rewards using this tool, and hope that this effort will lead to the

development of intervention programs that focus on specific aims and examine the effects on caregiver outcomes.

Conclusions

We validated the CCI in Japanese bereaved family members. The CCI was a valid scale having sufficient factor validity, internal consistency, test–retest reliability, and acceptable construct validity. The CCI comprises four perceived reward domains: 'mastery', 'appreciation for others', 'meaning in life', and 'reprioritization', and one perceived burden domain, evaluating both positive and negative aspects of caregiving consequences from the bereaved family member's perspective. As for discriminate validity, reward has little or no correlation with psychological distress. Thus, it is important to use perceived rewards as a measure for evaluation of caregiving consequences, as well as the caregiving burden, for improving the quality of the caregiving and bereavement experience.

Acknowledgements

Appendix

Caregiving Consequences Inventory

How do you feel about your caregiving experience with your family member? Please check the appropriate number. 1: absolutely disagree, 2: disagree, 3: somewhat disagree, 4: unsure, 5: somewhat agree, 6: agree, 7: absolutely agree. Through caring for your family member,

Mastery

I feel confident enough to manage future life changes.
I have learned to cope better with my life.
I came to accept some of the changes in my life.

Appreciation for others

I came to have more appreciation for others.
I became more aware of love from other people.
I came to place greater value on relationships.

Meaning in life

I came to find purpose and sense of meaning in my life.
I have a better outlook on my life.
I came to believe that there was meaning in life no matter what happened.

Reprioritization

I came to understand the brevity of life and appreciate each day.

I came to notice what is really important in my life.
I have learned the importance of being alive.

Burden

I felt a physical burden.
I sacrificed my own time and schedule.
I felt a mental burden.
I felt a financial burden.

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へるす出版

2. 癌患者にみられる代表的な精神症状とその対策

(3) せん妄

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はじめに

せん妄は，癌患者において頻度の高い精神症状であり，術後の30～40％，高齢入院患者の10～40％，終末期患者の30～90％程度に認められる(表1)[1]。せん妄は，患者自身にとって苦痛な症状であるのみならず，ルートやカテーテル類などの自己抜去，危険行動による事故，治療アドヒアランスの低下，適切な症状評価の障害，家族の精神的苦痛，家族とのコミュニケーションの妨げ，治療選択などに関する患者の意思決定の障害，医療スタッフの疲弊，入院の長期化などの多岐にわたる問題と関連することが指摘されており，適切なマネージメントが望まれる(表2)[2]。

本稿では，せん妄患者を適切にケアするうえでのマネージメントについて概説する。

せん妄の診断

せん妄は，軽度～中等度の意識混濁に，幻覚，妄想，興奮などさまざまな精神症状を伴う特殊な意識障害である。医療の現場では，前景に立つ多彩な精神症状のため，ストレス性/心因性の精神症状あるいは性格因に起因する行動異常などと誤解されることもまれではないが，本態は器質因に基づく意識障害であることに留意する必要がある。

表3にアメリカ精神医学会のせん妄の診断基準(DSM-Ⅳ)を示した[3]。せん妄は，何らかの身体的原因や薬剤により，脳機能が低下した状態であるため，ヒトのさまざまな精神機能が障害されることに起因するきわめて多岐にわたる症状が出現し得る。また，これらせん妄の症状は数時間～数日のうちに比較的急性に発症し，日内変動(例；とくに夜間に症状が増悪するなど)がみられるという特徴を有する。

せん妄の早期発見

せん妄のスクリーニング法としては，客観的な認知機能検査であるMini-Mental State Examination(MMSE)，看護ケアを通してアセスメントを行うツールとしてNEECHAM confusion scale(NCS)などがある。

表1　せん妄の有病率

対　象	患者数	有病率（％）	著者，発表年
一般住民（55歳以上）	810	1	Folstein, 1991
術後	2797	37	Bitondo, 1995 (26研究の文献レビュー)
高齢入院患者	－	10～40	Lipowski, 1987 (文献レビュー)
癌　入院・外来	215	4	Derogatis, 1983
緩和ケア病棟入院時	93	28	Minagawa, 1996
緩和ケア病棟入院時	104	42	Lawlor, 2000
緩和ケア病棟入院累積	104	68	
癌死亡6時間前	52	88	

表2　せん妄がもたらす影響

患者，家族の苦痛の原因
事故（ルート/カテーテル類の自己抜去，転倒，転落など）の原因
治療アドヒアランスの低下
症状評価の障害
家族とのコミュニケーションの妨げ
治療選択などに関する患者の意思決定の障害
医療スタッフの疲弊
入院の長期化

表3　せん妄の診断基準（アメリカ精神医学会）

診断基準	具体的な臨床症状
注意集中，維持，転導する能力の低下を伴う意識の障害（すなわち環境認識における清明度の低下）	質問に対して集中できない 前の質問に対して同じ答えをする 質問をしていても覚醒が保てず，すぐうとうとしてしまう
認知の変化（記憶欠損，失見当識，言語の障害など），またはすでに先行し，確定され，または進行中の認知症ではうまく説明されない知覚障害の出現	最近の記憶が曖昧である 新しいことをすぐに忘れてしまう 時間と場所に関する見当識を失っている 錯覚（壁のシミをみて「虫がいる」という），幻覚（人がいない場所に「人がいる」という）の存在 しばしば，幻覚を現実のものと確信し，不安・興奮の原因となる
その障害は短期間のうちに出現し（通常数時間から数日），1日のうちで変動する傾向がある	午前中おとなしく協調的であった人が，夜には点滴を抜いたり，ベッドから頻回に降りようとしたりする
病歴，身体診察，臨床検査所見から，その障害が一般身体疾患の直接的な生理学的結果により引き起こされたという証拠がある	背景に原因となる身体状態や薬剤の使用などがある

表4　せん妄と認知症の鑑別

	せん妄	認知症
意識	混濁	正常
発症	急性，亜急性（数時間～数日）	潜伏性，慢性（数カ月～数年）
経過	一過性	持続性
症状の動揺性	あり（夜間増悪）	目立たない
知覚の障害	錯覚，幻覚	目立たない
脳波	異常（広汎性徐波）	正常～軽度異常（軽い徐波）

しかし，実際には，せん妄は突然発現するわけではなく，注意深く観察すると，症状が顕在化する前に，さまざまな変化を示しているので，そのちょっとした変化に気づけるよう意識しておくことが重要であろう。

認知症との鑑別が問題となることもあるが，両疾患の鑑別診断のポイントを表4に示した。臨床的には，「ここ2～3日で急に惚けた」，「夜だけ不穏になる」などと表現される状態があるが，これらの多くはせん妄である。

せん妄の原因

せん妄の生物学的な発生機序ははっきりしていないが，臨床的には，せん妄の発生要因は，もともと存在する準備因子(せん妄の本態である脳機能の低下を起こしやすい状態)，誘発因子(せん妄の直接原因ではないが，せん妄の発症を促進，重篤化あるいは遷延化する要因)と直接原因に分けて考えることができる(表5)。

準備因子としては，年齢(高齢)，脳血管障害をはじめとする脳器質性疾患の既往，認知症(痴呆)や認知機能障害の存在などが代表的である。誘発因子としては，環境の変化，感覚遮断，睡眠・覚醒リズムの障害，治療上の身体拘束，強制臥床，不快な身体症状(疼痛，呼吸困難など)などの可能性が想定されている。直接原因としては，手術侵襲，薬剤，脱水，低酸素血症，感染症，血液学的異常(貧血，DIC，など)，代謝性異常(肝腎不全，高カルシウム血症，高/低血糖など)，脳の病変(脳炎，脳血管障害など)など，結果的に脳機能の低下をもたらすさまざまな要因があげられる。

進行・終末期の癌患者にせん妄が生じた場合は，多くの場合，複数の要因が原因となっていることが多いことが知られている。また，進行・終末期の癌患者にみられるせん妄の原因の中でも，薬剤性のものと高カルシウム血症によるものは原因への対応により，可逆性が高いことが知られている[1]。せん妄の原因薬剤として頻度が高いものは，オピオイド，ベンゾジアゼピン系薬剤，コルチコステロイドなどであることが示唆されている(表6)[4]。

表5　癌患者のせん妄の発現要因

	要　因	具体例
準備因子 (脳機能低下を起こしやすい状態)	年齢 脳の器質的病変の存在 認知機能障害	高齢（とくに70歳以上） 脳血管障害の既往 認知症
誘発因子 (発症を促進・重篤化・遷延化する要因)	環境の変化 感覚遮断 睡眠・覚醒リズムの障害 可動制限 不快な身体症状 心理的ストレス	慣れない入院環境 暗闇，視力・聴力障害 夜間の処置 身体拘束，強制臥床 疼痛，呼吸困難，便秘，排尿障害・尿閉 術前のうつ状態
直接原因 (せん妄そのものの原因)	腫瘍による直接効果 臓器不全による代謝性脳症 電解質異常 治療の副作用 薬剤性 感染症 血液学的異常 栄養障害 腫瘍随伴症候群	脳転移，髄膜播種 肝臓，腎臓，肺，甲状腺などの障害 高カルシウム血症，低ナトリウム血症 手術，化学療法，放射線療法 オピオイド類，抗うつ薬，ベンゾジアゼピン系薬剤(抗不安薬，睡眠薬)，抗コリン性薬剤，ステロイド 肺炎，敗血症 貧血 全身性栄養障害（低蛋白血症） 遠隔効果，ホルモン産生腫瘍

表6　薬剤性せん妄の原因の内訳

原因薬剤	割合（％）
オピオイド	54
ベンゾジアゼピン系薬剤	24
コルチコステロイド	21
H₂遮断薬	19
抗痙攣薬	6
抗ヒスタミン薬	4
抗コリン薬	6
その他	9

〔文献4）より引用〕

せん妄のマネージメント(表7)

A．原因の同定と治療

せん妄治療の原則は，原因の同定とそれに対する治療である。したがって，身体所見，検査所見，投薬内容の検討などから治療可能な原因を同定し，身体的原因の治療，原因薬剤の中止・減薬・変薬などを行うことにせん妄治療の本質がある。

原因に対する介入の具体的な例としては，オピオイドの減量あるいはオピオイドローテーション(モルヒネから他の強オピオイドへの変更)，脱水に対する適切な補液，高カルシウム血症に対するビスホスホネートの投与，感染症に対する適切な抗生物質の投与などがあげられる。しかし，痛みが適切にコントロールされていない場合には，患者の苦痛をいたずらに増幅しないためにオピオイドの安易な減量は避けるべきである。

終末期にせん妄が生じた場合は，原因となっている要因が治療可能であるか，また想定された治療が行われた場合の利益と不利益(有害事象や治療に伴う負担など)のバランスを医療チームで総合的に評価することが重要である。なお，死亡前24〜48時間に出現するものでは不可逆性であることが多い。

せん妄では，行動障害，認知障害の結果として，予期せぬ事故，転倒，転落，ドレーンやカテーテル類の自己抜去などがみられることもまれではない。そのため行動の危険性を評価し，患者周囲の危険物の撤去，頻回に訪床をするなど安全性を確保することも必要となる。

B．環境的・支持的介入

環境的・支持的介入も有用であるが，その一般的目標は，前述した，せん妄発現の促進因子を可能な限り軽減，除去することにある。例えば，親しみやすさと適切なレベルの環境刺激や感覚刺激を提供し，せん妄を増悪させる環境因子を除去する。

環境的介入の具体例としては，周囲のオリエンテーションがつくように夜間も薄明かりをつける，

表7　せん妄の医学的マネージメントの実際

	内容	具体的なマネージメントの例
医学的管理	原因の同定と治療	・身体的原因の治療 （高カルシウム血症に対するビスホスホネート投与，脱水に対する補液など） ・原因薬剤の中止・減薬・変薬 （オピオイドの減量あるいはオピオイドローテーション，睡眠薬の中止など）
	安全性の確保	・患者周囲の危険物（はさみなど）の撤去 ・頻回の訪床
環境的・支持的介入	環境的介入	・照明の調整（昼夜のめりはり，夜間の薄明かり：足元灯など） ・日付，時間の手がかり（カレンダー，時計を置くなど） ・眼鏡，補聴器の使用 ・親しみやすい環境の提供（家族の面会，自宅で使用していたものを置くなど）
	支持的介入	・積極的な身体症状緩和（除痛など） ・カテーテル類などを控える ・拘束を控える ・家族への説明，ケア
薬物療法	抗精神病薬による対症療法	・定型抗精神病薬（ハロペリドール，クロルプロマジンなど） ・非定型抗精神病薬（リスペリドン，クエチアピン，オランザピンなど）

表8　せん妄の薬物療法に使用される抗精神病薬の特徴

	定型抗精神病薬		非定型抗精神病薬		
一般名	ハロペリドール	クロルプロマジン	リスペリドン	クエチアピン	オランザピン
商品名	セレネース	コントミン，ウインタミン	リスパダール	セロクエル	ジプレキサ
投与可能な経路	経口，筋肉内，静脈内	経口，筋肉内	経口	経口	経口
初回投与量	0.75～2.5mg/回	10～25mg/回	0.5～1mg/回	25mg/回	2.5～5mg/回
常用量	0.75～10mg/日	10～50mg/日	0.5～4mg/日	25～100mg/日	2.5～10mg/日
半減期	10～24時間	10～59時間	4～15時間	3～6時間	21～54時間
代謝	肝	肝	肝	肝	肝
活性代謝産物	なし	あり	あり	なし	なし
代謝酵素	CYP2D6, CYP3A4	CYP2D6	CYP2D6	CYP3A4	CYP1A2, CYP2D6
作用特性・有害事象					
鎮静作用	低	高	低	高	高
抗コリン作用	低	高	低	低	低
降圧作用	低	高	低	低	低
錐体外路症状	高	低	低	低	低
その他	・標準的薬物 ・全剤形より選択可能	・治療効果に対するエビデンスは同等	・腎排泄であり腎不全で使用注意	・Parkinson病のせん妄に第一選択	・ステロイド併用注意

時間の感覚を保つことができるよう，カレンダーや時計を置く，親しみやすい環境を整えるために家庭で使い慣れたものを置く，などがあげられる。また，家族や慣れ親しんだ医療スタッフとの接触を頻回にすることで安心感を与えることも有用である。支持的な介入としては，可能な限りカテーテル類を控えたり，積極的に不快な身体症状を緩和するなどの対応が有用な介入となり得る。

せん妄を呈している患者を前に家族は動揺していることが多く，せん妄とその原因，経過，治療について家族に適切な説明を行うことも重要である。

C．身体的介入（薬物療法）

せん妄の原因の同定やその治療が困難であったり，治療に時間を要することが想定される場合には，対症療法として薬物療法が行われる。

せん妄の薬物療法の有用性に関する無作為化比較試験は内外を通して3報のみであるが，その結果，ベンゾジアゼピン系薬剤に比べ，ハロペリドールあるいはクロルプロマジンといった抗精神病薬のほうがせん妄の治療には効果的であること，および現時点において抗精神病薬の中で特定の薬物が優るという根拠はないことが示されている[3]。したがって，薬物療法の中心は，原則的には抗精神病薬であり，実地臨床においては，なかでもブチロフェノン系抗精神病薬であるハロペリドールが繁用され

ている。ハロペリドールはせん妄における精神運動興奮や幻覚・妄想に対して有効性が高く、またベンゾジアゼピン系薬剤と比較して意識レベルを下げることなく鎮静が図れ、呼吸・循環器系への有害事象が少なく、経口投与に加え筋肉内投与や経静脈的投与も可能であるなどの特徴を有する。とくにハロペリドールを点滴投与する場合、1アンプル（5mg）単位の投与は、過量投与になる場合もあるので、治療初期には少量を頻回投与することにより必要最小量を推定し、翌日からの投与量の参考にすることが推奨される。ハロペリドールが無効な場合や興奮が強いときには、フェノチアジン系抗精神病薬であるクロルプロマジンを用いるが、心・血管系への影響、とくに血圧の低下には注意が必要である。これら薬剤はせん妄症状の改善後、数日程度は維持し、その後、投与量を1/2～1/3程度に漸減していき中止する。また、ハロペリドール、クロルプロマジンなどの定型抗精神病薬に加えて、リス

ペリドン、クエチアピン、オランザピンといった新しい非定型抗精神病薬も有用であることが示唆されている。現在、わが国で使用可能な抗精神病薬の中でせん妄治療に繁用される薬剤の特徴を表8に示した。

まとめ

せん妄は、頻度の高い、多彩な精神症状を随伴した特殊な意識障害である。せん妄の予防は現状では難しいことに加え、看過されると事故をはじめとした多岐にわたる問題の原因となり得るため、せん妄に対する正しい理解に基づく、早期発見と早期対応が求められる。適切な対応としては、原因の同定と治療、環境的・支持的介入、薬物療法があげられる。

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