

Psychological Distress among Caregivers for Patients Who Die of Cancer: A Preliminary Study in Japan

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Background: In Japan, little is known of the severity of and factors associated with psychological distress among caregivers of patients with advanced or recurrent cancer who die.

Methods: This prospective cohort study of cancer patients at the National Cancer Center Hospital East, Japan, and their caregivers followed the participants from the initial palliative care consultation (T1) to 6 months (T2) and 13 months (T3) after the patient's death. At T1, patients and caregivers were interviewed separately. After T1, telephone interviews were conducted periodically, and a mail survey was distributed at T2 and T3. The Patient Health Questionnaire-9 (PHQ-9) was used to assess depression, and the Distress and Impact Thermometer (DIT) was used to screen for psychological distress. Items on end-of-life attitudes, including awareness, discussion, and willingness of cancer care and death, were developed.

Results: Thirty-one of 86 eligible pairs participated in this study. The participation rate was low (36%) and enrollment was thus halted. Data were collected up to T3 for 22 pairs (completion rate 71%). PHQ-9 scores at T2 and T3 were higher than at T1, but the difference was not significant ($p = 0.07$). PHQ-9 score at T3 was significantly associated with caregiver PHQ-9 and distress at T1, with patient distress and impact at T1, and with caregiver health problems at T2.

Conclusions: Caregiver depression persisted up to 13 months after the patient's death, which suggests that pre-bereavement screening with the DIT might be useful. The present paired enrollment process requires improvement. (*J Nippon Med Sch* 2022; 89: 428–435)

Key words: caregiver, cancer patient, psychological distress, prospective cohort study, post-bereavement

Introduction

A prospective cohort study of more than 300 pairs of cancer patients and their caregivers was conducted at seven sites across the United States. The study monitored

participants from the time of cancer progression or recurrence to the period after the patient's death and yielded many findings on the psychological distress of patients and caregivers. The prevalence of depression among

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caregivers was 5% at 4.5 months before the patient's death¹ and 7% at 6 months after death². At 6 months after the patient's death, the prevalence of depression among bereaved family members was approximately four times higher when patients had not engaged in discussions with physicians before their death and received aggressive treatment, such as cardiopulmonary resuscitation, ventilatory management, and admission to an intensive care unit, at the end of life². A prospective cohort study reported that discussions between patients and physicians about end-of-life (EOL) care, and the actual content and cost of EOL care received³, were associated with the severity of emotional distress of the bereaved family after death².

A cross-sectional study of mental distress among bereaved families of Japanese cancer patients showed that mental health problems were present in about half the bereaved families at up to 7 years after the death of their family member⁴, and a nationwide survey found that 17% of bereaved families in palliative care wards were depressed⁵. However, because no longitudinal studies have examined change in caregivers' psychological distress during the interval from illness to death, little is known regarding pre-bereavement factors associated with their psychological distress. Furthermore, no study of patient/caregiver pairs has enrolled patients with advanced or recurrent cancer, so data on EOL attitudes toward treatment, death, and bereavement are limited.

To determine the severity of and factors associated with psychological distress among caregivers before and after the death of a family member, this preliminary review of prospective cohort studies investigated the EOL attitudes of patients with advanced/recurrent cancer and their caregivers in Japan.

Materials and Methods

Study Sample

This preliminary prospective cohort study examined psychological distress among caregivers of patients with advanced or recurrent cancer who were treated at the National Cancer Center Hospital East (NCCHE). The study was approved by the Institutional Review Board and Ethics Committee of the National Cancer Center of Japan in March 2014 (2013-258).

The inclusion criteria were that this was the patient's first visit to the outpatient clinic of the Department of Palliative Medicine, NCCHE, that they were 20 years of age or older, and that they had received a diagnosis of advanced or recurrent cancer. Cancer patients and

caregivers were included if both parties consented. Patients were excluded if they were physically or mentally unable to tolerate the baseline survey or unable to read, write, or speak Japanese sufficiently to complete the questionnaire. In addition, caregivers were excluded from the post-bereavement follow-up (T2 and T3) if they were cognitively impaired (score of 23 or lower on the Mini Mental State Examination [MMSE] cognitive function test) at the time of the initial survey (after the patient's first visit to the outpatient clinic of the Department of Palliative Medicine). The caregiver was defined as the person identified by the patient as providing the greatest amount of unpaid private care for the patient.

Procedure

The researchers (physicians in palliative medicine) sampled a series of outpatients. Among those initially considered eligible for this study, the physicians excluded those judged to be physically or mentally incapable of participating in the study, and then asked the rest to participate. If they agreed, two research assistants interviewed patients and caregivers separately, because of their mutual concern for each other. Consent for participation was obtained and the T1 assessment was conducted on the day of the first outpatient visit. Thereafter, the research assistants made regular telephone calls, every 2 to 3 months, to identify the date and place of the patient's death. Subsequent telephone calls were made periodically, and mail surveys were conducted at 6 and 13 months after death (T2, T3). No rewards were paid to the participants. The rationale for the three assessment time points before and after bereavement in this study is as follows: T1 is the time point when both patient and caregiver can be interviewed, T2 is based on the time point when psychological distress was assessed in the US caregiver study², and it is the time point when the ICD-11 (2022)⁶ Prolonged Grief Disorder states that the grief reaction lasts for at least 6 months. T3 is based on the DSM-5 (2013)⁷ Persistent Complex Bereavement Disorder (categorized as 'Conditions for Further Study'), which states that the grief reaction lasts for at least 12 months, and that 12 months after bereavement is the one-year anniversary, which is an anniversary reaction. We chose 13 months, one month after that, because psychological distress has been reported to intensify.

We initially conducted a 2-week recruitment test in July 2014, but the participation rate was low (39%; 7 of 18 eligible applicants). After careful consideration, the authors revised the procedure manual and again conducted recruitment from January through March 2015.

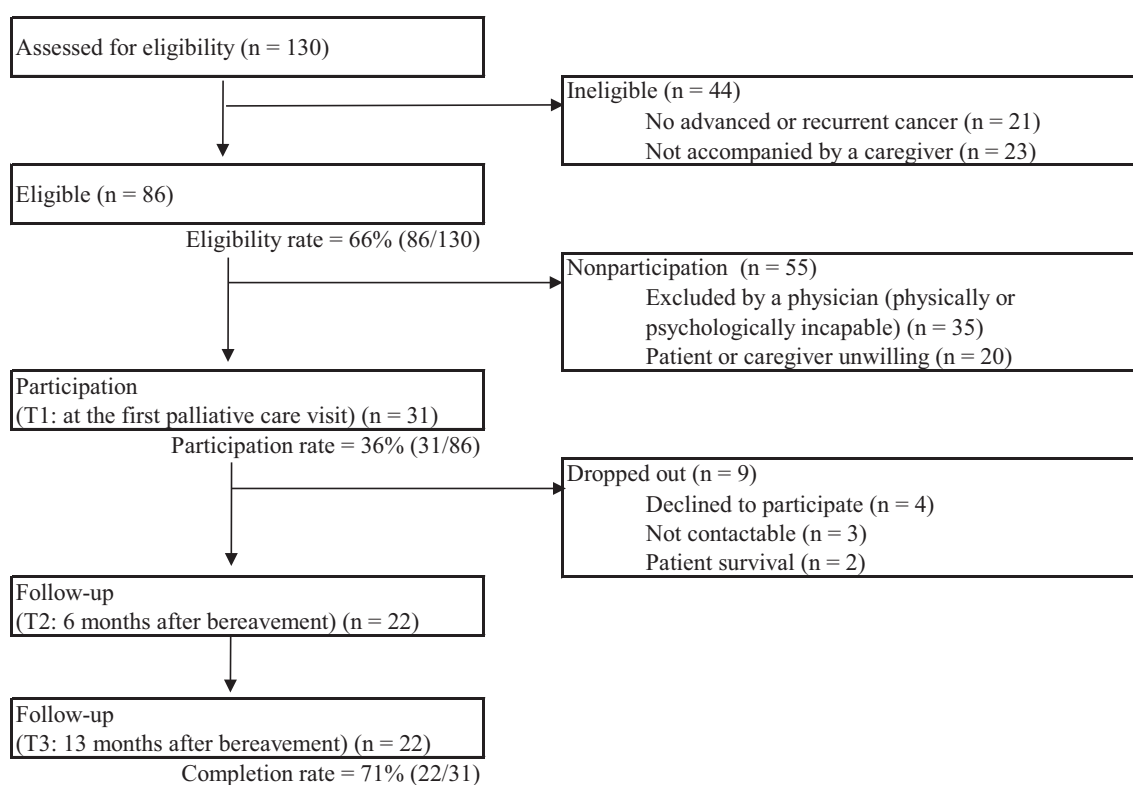


Fig. 1 Flow of study sample

The results for the two periods were combined because we did not modify the eligibility criteria, but merely detailed procedures and assignments to facilitate implementation. As shown in **Figure 1**, the eligibility rate was 66% (86/130), the participation rate was 36% (31/86), and the completion rate was 71% (22/31). Because the participation rate did not improve, further entries were suspended. In the follow-up research, if a patient's death could not be confirmed as of July 2016, the T2 and T3 surveys were ended at that time; all T3 surveys were ended in July 2017.

Measures

Psychological distress

The Patient Health Questionnaire-9 (PHQ-9) is a diagnostic aid for psychiatric disorders, such as depression, that are common in primary care. It can be administered in 1-2 minutes⁸ and measures the frequency of nine common symptoms of major depression, including mood, sleep, fatigue, and appetite. The frequency of each of these nine symptoms during the last 2 weeks is rated on a four-point scale (0: never occurring, 1: occurring on a few days, 2: occurring on more than half of days, 3: occurring almost every day or more).

The Distress and Impact Thermometer (DIT) is a self-administered questionnaire that screens for feelings of psychological distress in cancer patients. It can be admin-

istered in 1-2 min and consists of two questions on distress and impact in the past week. Responses are made by using an 11-point Likert scale from 0 to 10. The cut-off values for distinguishing a case of adjustment disorder or depression from those without a psychiatric diagnosis were a score of 4 or higher for irritability and a score of 3 or higher for disturbance (sensitivity, 0.82; specificity, 0.82)⁹.

Cognitive function

The MMSE is the most widely used cognitive functioning test globally and is designed to assess cognitive function from multiple perspectives in 10 subtests administered by interview. The reliability and validity of the Japanese version of the MMSE have been verified, and a score of 23 or lower on a 30-point scale is considered to indicate cognitive impairment¹⁰.

EOL attitudes

Six items, including awareness, discussion, and willingness of cancer care and death, were assessed with a four-point Likert-type scale (0: not at all, 1: not much, 2: a little, 3: enough). For each item, patients and caregivers were instructed to choose the option that best applied to them. The instructions were as follows. For cancer treatment: "Have you ever thought about the future of your treatment, for example, where you would like to receive your treatment (home, hospital, palliative care ward, etc.)

and whether you would like to receive so-called life-prolonging treatment (cardiopulmonary resuscitation, intensive care, etc.)?" For death: "Have you ever thought about the future of your family, for example, what you want to leave to your family or what you want to tell them?"

Statistical Analysis

Each item for EOL attitude was recorded as 0 ("not at all" and "not much") or 1 ("a little" and "enough"), after which the full match rate was calculated. Differences in psychological distress of caregivers at the three time points were assessed by the nonparametric Friedman's rank test. To examine factors associated with caregiver psychological distress, Spearman's ρ was calculated to examine correlations of nonparametric variables. Here, a p value of less than 0.05 was considered to indicate statistical significance. All p values are two-tailed. All statistical analyses were done with SPSS version 27.0 (IBM Corporation).

Results

Characteristics of Cancer Patients and Their Caregivers

As shown in **Table 1**, the first visit to the Department of Palliative Medicine occurred a median of 2 months before the patient's death. In this study, 9 (29%) caregivers were male, 24 (77%) caregivers were the patient's spouse, and 14 (45%) patients died at home. The numbers of caregivers above the cut-off for depression, as determined by the PHQ, were 4 (13%) at T1, 6 (27%) at T2, and 3 (14%) at T3.

EOL Attitudes toward Cancer Care and Death

As shown in **Table 2**, 60% of participants gave a response of "a little" or "enough" for all items on EOL attitudes, and the overall rate of agreement between patients and caregivers was greater than 60%. The item "I discussed bereavement with my family" had a lower implementation rate than the other items and a lower overall agreement rate.

Change in Psychological Distress Scores among Caregivers

As shown in **Table 3**, median PHQ-9 values were higher at T2 and T3 than at T1, but the ranks of the means did not significantly differ among the three time points. The mean rank for DIT did not significantly differ among the three time points.

Factors Associated with Psychological Distress among Caregivers

As shown in **Table 4**, caregiver PHQ-9 score at 13

months after the patient's death (T3) was significantly associated with caregiver PHQ and DIT scores at T1 and T2, and with health problems at T2. EOL attitudes were not significantly associated with any of these variables.

Discussion

This is the first prospective cohort study to examine Japanese cancer patients and their caregivers from the initial palliative care consultation to the period after the patient's death. Unfortunately, the study had to be halted because the participation rate did not improve.

In a similar study conducted in the United States², 917 patients were eligible after approximately 5.5 years of recruitment at seven sites. In contrast, 86 patients were eligible in 3.5 months in the present study, which is more than 12 times the eligibility rate of the US study, when numbers per site per year are compared. Therefore, the recruitment setting was appropriate. However, the participation rate was 36% in this study, as compared with 70% in the American study. Because this rate did not improve after modifying the method, the procedure for requesting participation in studies such as this should be improved in future research. In the US study, participation was requested by an oncologist when the first anti-cancer drug treatment was deemed ineffective; however, in the present study, the request was made when a palliative physician first met the patient in an outpatient clinic of the Department of Palliative Medicine. Therefore, the fact that many patients were deemed unsuitable for the study limited the data collected from patients and their families. The participant completion rate in this study was adequate, at 71%, which is attributable to regular telephone contact by the research assistants. Telephone follow-up is advantageous because it reduces the number of participants who withdraw, but contacting caregivers before and during bereavement is a psychological burden for the research assistants and requires psychological support skills. Another problem was that the principal investigator was not always available at the study site. To improve the participation rate, a greater number of researchers must be available at all times. Thus, implementation of a prospective cohort study requires long-term human resource recruitment and the associated expenses.

Because this study was interrupted, the number of participants was insufficient for quantitative analysis. Therefore, we conducted only a preliminary analysis using nonparametric methods. Regarding the EOL attitudes of patients and caregivers, both implementation and agree-

Table 1 Characteristics of cancer patients and their caregivers

	Patients	N = 31 (T1)	Caregiver	N = 31 (T1), N = 22 (T2, T3)
	Mean ± SD (median, range)	n (%)	Mean ± SD (median, range)	n (%)
Age, years	68 ± 9.9 (67, 44-87)		63 ± 12 (65, 37-81)	
Sex, male		19 (61)		9 (29)
Relationship				
Spouse				24 (77)
Child				5 (16)
Other				2 (6)
Cancer site				
Breast		5 (16)		
Head and neck		5 (16)		
Lung		4 (13)		
Stomach		3 (10)		
Esophagus		3 (10)		
Uterus and ovary		3 (10)		
Colon		2 (6)		
Others		6 (19)		
Cancer stage				
III		3 (10)		
IV		11 (35)		
Recurrence		17 (55)		
Psychological distress				
PHQ-9, >10 at T1		5 (16)		4 (13)
PHQ-9, >10 at T2				6 (27)
PHQ-9, >10 at T3				3 (14)
DIT, >4/3 at T1		11 (36)		10 (32)
DIT, >4/3 at T2				6 (27)
DIT, >4/3 at T3				7 (32)
MMSE, ≤23 at T1		5 (16)		0
Time from T1 to death, days	138 ± 164 (64, 5-523)			
Days at home in the last month	21 ± 9.5 (24, 0-30)			
Place of death				
Home		14 (45)		
General ward of NCCHE		16 (52)		
Palliative care unit of NCCHE		1 (3)		
History of any psychiatric disorder, presence		6 (19)		2 (6)
Living status, alone with the patient				9 (29)
Employment status, full time or part time		7 (23)		
Education, more than 10 years		24 (77)		28 (90)
Involvement in patient care, every day				18 (58)

Note: Some percentages do not add up to 100% because of missing data.

Abbreviations: SD: standard deviation, PHQ: Patient Health Questionnaire, DIT: Distress and Impact Thermometer, MMSE: Mini Mental State Examination, NCCHE: National Cancer Center Hospital East

ment rates were generally high, at over 80%. An American study reported that 37% of patients had an EOL discussion with their physician at 4.5 months before the patient's death, this shared decision-making between physicians and cancer patients is necessary to reduce the psychological distress of the bereaved family². In Japan, tools have recently been developed to support decision-making in cancer care¹¹. The present study examined dis-

cussions between patients and caregivers rather than with physicians and found that discussions were adequate at about 2 months before death. However, the number of bereaved family members who said they were able to discuss the patient's death was lower than for the other items. We hypothesized that the congruence or discrepancy between caregiver and patient EOL attitudes would be related to caregivers' psychological distress af-

Table 2 EOL attitude toward cancer care and bereavement (n = 31 pairs)

		Not at all/not much (0/1) n (%)	A little/enough (2/3) n (%)	Coincidence full match (%)
Awareness of cancer care	Patient	4 (13)	27 (87)	81
	Caregiver	2 (6)	29 (94)	
Discussion about cancer care with family	Patient	7 (23)	24 (77)	68
	Caregiver	5 (16)	26 (84)	
Willingness to discuss cancer care with family	Patient	3 (10)	28 (90)	84
	Caregiver	1 (3)	29 (97)	
Awareness of bereavement	Patient	7 (23)	24 (77)	65
	Caregiver	6 (19)	25 (81)	
Discussion about bereavement with family	Patient	9 (29)	22 (71)	65
	Caregiver	12 (39)	19 (61)	
Willingness to discuss bereavement with family	Patient	4 (13)	27 (87)	84
	Caregiver	3 (10)	28 (90)	

Abbreviation: EOL: end of life

Table 3 Change in scores of psychological distress among caregivers

		T1	T2	T3	p-value (Friedman's rank test)
		Average rank (median) n = 31	Average rank (median) n = 22	Average rank (median) n = 22	
PHQ-9	Total score (0–27)	1.66 (3.00)	2.18 (7.50)	2.16 (6.00)	0.07
DIT	Distress (0–10)	2.23 (5.00)	2.02 (3.00)	1.75 (3.00)	0.21
	Impact (0–10)	1.89 (1.00)	2.00 (2.00)	2.11 (2.00)	0.69

Abbreviations: PHQ: Patient Health Questionnaire, DIT: Distress and Impact Thermometer

ter bereavement, but we were unable to detect an association in this study. However, the sample size of this study was insufficient to test that hypothesis, and further research is needed.

With regard to psychological distress, the participants' selection bias should first be considered. In other words, because palliative physicians did not ask patients with psychological distress at T1 to participate in the study, and because some participants withdrew from the study at T2 because of psychological distress, those who were able to complete T3 in this study may have had less psychological distress. As for change over time, psychological distress was greatest at T2, followed by T3 and then T1, but the nonparametric test showed no significant difference in relation to time point. Future larger-scale studies are needed.

Analysis of factors associated with psychological distress among caregivers indicated that DIT before the patient's death might predict depression at T3, 13 months after the patient's death. Because the number of health problems at 6 months after the patient's death was associated with depression at T3, it is also important to as-

sess health problems during this period. According to the International Classification of Diseases-11 of the World Health Organization⁶, one diagnostic criterion for prolonged grief syndrome is that symptoms persist for longer than 6 months after the start of bereavement. It may be desirable for staff at medical institutions to conduct a brief evaluation to ensure that bereaved family members with depression can access treatment during the interval between 6 months and 1 year after the patient's death.

Regarding study limitations, this study was planned as a prospective cohort study but was interrupted because of the low participation rate. First, selection bias is a concern, which is not the case for studies with sufficiently high participation rates. As a result, the present participants might have lower-than-average levels of psychological distress. Second, sample bias is also a concern because the study was conducted at a single center. Third, we did not examine the association between depression in bereaved families and bereavement, it is possible that depression may be caused by a variety of reasons other than bereavement.

Table 4 The correlation matrix between variables (Spearman's ρ)

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	
1 PHQ-9	—																		
2 Care-giver	3.00	—																	
3 DIT (Distress)	7.50	0.520*	—																
4 DIT (Impact)	6.00	0.760**	0.724**	—															
5 MMSE	5.00	0.571**	0.429*	0.589**	—														
6 EOL attitude toward cancer care	1.00	0.419*	0.175	0.373	0.512**	—													
7 EOL attitude toward bereavement	29.0	0.156	0.052	-0.116	-0.023	-0.064	—												
8 EOL attitude toward bereavement	10.0	-0.227	0.048	-0.156	-0.270	-0.075	-0.229	—											
9 Days of care per week	9.00	0.034	0.104	0.117	0.115	0.065	-0.159	0.713**	—										
10 Days at home in the last month	4.00	0.078	0.163	0.213	0.107	0.242	-0.243	-0.069	0.275	—									
11 Number of health problems	24.0	-0.033	0.154	0.099	0.198	-0.082	0.160	-0.156	0.062	0.088	—								
12 Number of health problems	1.00	0.438*	0.564**	0.495*	0.298	-0.178	0.071	0.126	0.197	-0.123	-0.077	—							
13 PHQ-9	0.50	0.225	0.417	0.371	0.332	0.082	0.002	0.183	0.193	-0.150	-0.038	0.658**	—						
14 DIT (Distress)	6.00	0.193	0.021	0.381	0.093	-0.146	-0.146	0.100	0.153	0.024	-0.272	0.017	0.075	—					
15 DIT (Impact)	5.00	0.251	0.403	0.514*	0.438*	0.214	0.045	0.015	0.328	0.124	-0.034	0.163	0.247	0.161	—				
16 MMSE	2.00	0.217	0.268	0.615**	0.358*	0.287	-0.030	-0.162	0.127	0.141	0.058	0.037	0.176	0.281	0.657**	—			
17 EOL attitude toward cancer care	28.0	-0.135	0.107	-0.157	0.040	0.092	0.148	0.236	0.209	-0.047	0.091	0.121	0.169	-0.119	0.049	-0.071	—		
18 EOL attitude toward bereavement	10.0	0.105	0.301	0.133	-0.195	-0.081	0.120	0.690**	0.558**	0.096	0.120	0.138	0.266	0.083	0.066	-0.087	0.281	—	
19 EOL attitude toward bereavement	9.00	0.199	0.090	0.189	-0.149	-0.176	0.200	0.446*	0.343	-0.081	0.280	0.125	0.052	0.138	0.211	0.061	0.193	0.584**	—

Note: Number of health problems: Health problems range from 0 to 8 regarding eight items: diet, weight, sleeping time, sleeping pills, alcohol, tobacco, hospital visits, and hospitalization.

Abbreviations: PHQ: Patient Health Questionnaire, DIT: Distress and Impact Thermometer, MMSE: Mini Mental State Examination, EOL: end of life

*p<0.05, **p<0.01

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Conflict of Interest: None declared.

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