

Validity and Reliability of the Japanese Version of the Caregiver Reaction Assessment Scale (CRA-J) for Community-Dwelling Cancer Patients

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Background: The aim of this study was to validate the Caregiver Reaction Assessment (CRA) among caregivers of community-dwelling advanced cancer patients in Japan. **Methods:** A cross-sectional questionnaire was administered to advanced cancer patients and their caregivers who were cared for at day hospices and home palliative care services. We translated the CRA into Japanese, and then verified factor validity, reliability, construct validity, concurrent validity, and known groups' validity. To address construct and concurrent validity, we calculated Pearson's correlation coefficient between the Japanese version of the CRA and the Burden Index of Caregivers (BIC). To address known groups' validity, we used the *t* test or analysis of variance

(ANOVA). **Results:** A total of 57 caregivers participated in the study. Five factors were extracted ("impact on schedule," "caregiver's self-esteem," "lack of family support," "impact on health," and "impact on finances") and reliability was good. Construct and concurrent validity among the subscales of the BIC were good. Regarding known groups validity, the subscale score of "impact on schedule" for the groups that cared 6 hours or more per day was higher than the other group ($P = .04$). **Conclusion:** The CRA-J is valid and reliable. This scale is useful for caregivers of cancer patients in Japan.

Keywords: palliative care; neoplasms; quality of life; caregiving; home care services; day hospice

Introduction

It is important for advanced cancer patients to be able to remain in their favorite place, but there are

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many barriers to achieving this goal. According to a survey in Japan, 91% of cancer patients died in hospitals at 2007. Of these patients, 6% died in hospices or palliative care units. Meanwhile, only 6% of cancer patients died in their own home.^{1,2} Previous studies have pointed out the barriers to remaining at home for advanced cancer patients, and one of the barriers is burden on the family.³⁻⁵

In the West, day hospices and home palliative care services serve an important role in easing the burden on the families of patients who are cared for at home.⁶⁻¹² But in Japan, as such services are just getting started, only a few pioneering facilities offer them. Consequently, the burden on family caregivers of patients who receive day hospice or home palliative care services is not well understood.

Additionally, few studies have examined the caregiver burden for patients with advanced cancer, and there is no standard scale to evaluate the care burden on family caregivers in Japan. The Zarit Burden Interview (ZBI) has been validated and is in widespread use in Japan.¹³⁻²¹ However, the ZBI does not include some important aspects involved in caring for cancer patients, such as financial burden. Therefore, the ZBI might not be suitable. In addition, in recent years, studies have increasingly reported on the beneficial effects of caregiving.²²⁻²⁷ However, very few scales focusing on both the positive and negative aspects of caregiving have been developed in Japan for the caregivers of community-dwelling advanced cancer patients.

In contrast, the Caregiver Reaction Assessment (CRA) has been used in a large number of studies in Western countries for caregivers of cancer patients.²⁸⁻³⁴ The CRA is a multidimensional scale and consists of 5 subscales. The CRA would probably be useful in Japan, but the Japanese version of the CRA (CRA-J) has not been validated. Therefore, the aim of this study was to verify the validity and reliability of the CRA-J among caregivers of community-dwelling advanced cancer patients.

Methods

Participants and Procedures

A cross-sectional questionnaire was administered to caregivers of community-dwelling advanced cancer patients. In all, 3 day hospices and 8 home palliative care clinics/visiting nurse stations in Miyagi Prefecture, Hiroshima Prefecture, and the Tokyo Metropolitan Area participated in this study. The inclusion criteria for primary caregivers of advanced cancer patients were as follows: (1) patient had to have advanced cancer, (2) patient was aged 20 years old or more, (3) patient used these institutions 2 or more times, (4) caregiver had to be a family member who had been providing the most care, and (5) caregiver was aged 20 years or more.

The study physicians or nurses explained the aims of study to the participants who signed consent forms. We asked that the primary caregiver complete the caregiver questionnaire. We gave a coupon book worth 1000 yen (US\$9.55) to participants. In addition, a study physician or nurse filled out the medical information sheet. This study was conducted from September 2006 to March 2007. The ethical and

scientific validity of this study was approved by the institutional review boards of the University of Tokyo.

Measurements

Caregiver Reaction Assessment. Two independent forward translations by native Japanese speakers fluent in English led to the first Japanese consensus version. Two independent backward translations of the consensus Japanese version were prepared by bilingual native Japanese speakers who had no access to the original English version. These Japanese backward translations were reviewed together with 2 of the authors. The Japanese consensus version was finally revised with input from all forward and backward translators. This translation obtained approval from the original author (CWG).

The original CRA consists of 24 items, which can be divided into 5 subscales: caregiver's self-esteem, impact on schedule, lack of family support, impact on health, and impact on finances. The subscale "caregiver's self-esteem" has 7 items that measure the extent to which caregiving imparts individual self-esteem. The subscale "impact on schedule" has 5 items that measure the extent to which caregiving interrupts usual activities, causes the elimination of some activities, and interferes with relaxation time. The subscale "lack of family support" has 5 items that assess the extent to which the family supports and works together with the caregiver. The subscale "impact on health" has 4 items that measure the caregiver's physical capability and energy to provide care. It also assesses the caregiver's health in relation to the caregiving role. The latter 4 subscales assess negative experiences of caregiving. The final subscale "impact on finances" has 3 items that look at the adequacy, difficulty, and strain on the financial situation of the caregiver and family.

*The Burden Index of Caregivers.*³⁵ A care burden scale for caregivers of patients with intractable neurological disease or stroke developed by Miyashita, comprises 11 items assessed by a 4-point Likert scale to provide a total score of 0 to 44, with a higher score representing a greater care burden. The Burden Index of Caregivers (BIC) is short and thought to be suitable for Japanese caregivers. The BIC is a self-reported questionnaire that measures the

burden experienced by caregivers. It includes 5 domains and an overall care burden question.

Regarding demographic factors, we collected information on the caregiver's age, gender, working status, hospital visits according to the illness the caregiver had, relationship to the patient, duration of caregiving, minutes per day spent caring for the patient, minutes required for close supervision of the patient, and household income. Income was categorized into 1 of 5 levels.

Analysis

First, we performed an item analysis to confirm the presence or absence of the ceiling or floor effect. The floor or ceiling effect means that most of the answers are biased to the lowest or highest points, respectively, so that the measurement has little meaning for the items of the scale. We then verified the validity and reliability of the CRA-J. We calculated the descriptive statistics for scores of each item. We then performed explanatory factor analysis (least-squares method with a promax rotation) to examine factor validity and examined reliability using Cronbach's α coefficient. To address construct and concurrent validity, we calculated Pearson's correlation coefficient among the CRA-J and preexisting BIC subscales. We assumed domains that were correlated between the 2 assessments were as follows: "impact of schedule" and "time-dependent burden," "caregiver's self-esteem" and "emotional burden," "caregiver's self-esteem" and "existential burden," and "impact on health" and "physical burden." Known groups' validity was examined by *t* test or trend test. Regarding "impact of schedule," "caregiver's self-esteem," "lack of family support," and "impact on health," we divided participants into 2 groups according to minutes per day spent caring for the patient and then examined the results of the *t* test.

All statistical tests were done with a significance level .05 and a 2-tailed test. All analyses were performed using the statistical package SAS version 9.1 (SAS Institute, Cary, NC).

Results

Participant Characteristics

A total of 57 caregivers participated in the study. We show the participants' characteristics in Table 1. The mean age \pm SD of the patients was 73 ± 12 years

Table 1. Participant Characteristics

	n	%
Patients		
Age, y, mean \pm SD	73 ± 12	
Gender (male)	26	46
Length of service use, wk, mean \pm SD	27 ± 35	
Opioid use	22	39
Chemotherapy	12	21
Intravenous hydration therapy	9	16
Oxygen therapy	11	19
Metastasis	41	72
ECOG Performance scale		
0	3	5
1	7	13
2	15	27
3	16	29
4	15	27
Caregivers		
Age, y, mean \pm SD	57 ± 13	
Gender (male)	12	23
Working status (employed)	29	57
Hospital visit according to the illness the caregiver had	21	41
Relationship (spouse)	27	52
Length of caregiving, mo, mean \pm SD	22 ± 38	
Time spent on care per day, min, mean \pm SD	458 ± 418	
Time required for close supervision of the patient per day, min, mean \pm SD	224 ± 345	
Household income per year		
<2 million yen	5	11
2 to <4 million yen	14	30
4 to <6 million yen	8	17
6 to <8 million yen	9	19
8 to <10 million yen	5	11
≥ 10 million yen	6	13

and the proportion of men was 46%. The mean age of the caregivers was 57 ± 13 years and the proportion of men was 23%. The relationship between patient and caregiver was spouse in 52% of the participants. Of the caregivers, 57% were employed. The average duration of caregiving was 22 ± 38 months, and the average time per day spent on care was 458 ± 418 minutes.

Item Analysis

After we confirmed the face validity and content validity of the CRA-J, we checked the presence or

Table 2. Factor Analysis

	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5	Communality
Impact on Schedule						
Visit family/friends less	0.85	0.01	0.12	-0.07	-0.15	0.73
Activities centered on care	0.83	0.14	0.07	-0.19	-0.09	0.60
Eliminate from schedule	0.77	-0.11	-0.15	0.14	0.15	0.73
Stop work to care	0.75	0.03	0.04	0.05	0.12	0.63
Interruptions	0.69	-0.05	0.00	0.19	0.14	0.69
Caregiver's self-esteem						
Privilege to care	0.04	0.89	0.01	0.18	-0.15	0.77
Caring is important to me	0.01	0.80	-0.05	0.10	0.08	0.64
Want to care	0.05	0.76	-0.18	0.12	-0.03	0.62
Caring makes me feel good	-0.25	0.72	0.12	-0.21	0.11	0.77
Enjoy caring	0.07	0.63	0.04	-0.22	0.06	0.48
Lack of family support						
Family left me alone	-0.07	0.04	0.87	0.14	0.00	0.76
Others avoid caring	-0.02	-0.08	0.74	0.21	0.00	0.65
Feel abandoned	0.16	-0.04	0.74	-0.19	0.15	0.74
Difficult to get help	0.10	0.01	0.74	0.03	-0.05	0.57
Impact on health						
Health has gotten worse	0.04	0.10	0.13	0.64	0.14	0.49
Tired all the time	0.46	-0.02	0.06	0.53	-0.14	0.76
Impact on finances						
Financial strain on family	0.14	0.06	-0.04	0.04	0.97	0.95
Difficult to pay	-0.16	-0.05	0.29	0.07	0.65	0.66
Cumulative proportion of variance explained						0.77

absence of the ceiling or floor effect. No items demonstrated a ceiling effect or floor effect.

Factor Validity

When we performed exploratory factor analysis, the result of our factor structure was not the same as the original one. Next, we excluded the reversed scored items. However, item 18 (physical strength) contributed to the subscale "impact on schedule." Consequently, we excluded the reversed scored items and item 18 (physical strength) and got the result in Table 2 because of the Japanese cultural characteristics and statistical nature. Five factors were extracted, and the cumulative proportion of variance explained was 76.6%.

Reliability

One domain's Chronbach's α coefficient was slightly low ($\alpha = .73$), but the reliability of the other domains were high (0.83–0.89; Table 3).

Construct and Concurrent Validity

The pre-assumed correlations before the study were "impact on schedule" and "time-dependent burden"

Table 3. Reliability

Factor	Cronbach's α Coefficient
Impact on schedule	.89
Caregiver's self-esteem	.87
Lack of family support	.88
Impact on finances	.83
Impact on health	.73

($r = .75$), "caregiver's self-esteem" and "emotional burden" ($r = .66$), "caregiver's self-esteem" and "existential burden" ($r = .54$), and "impact on health" and "physical burden" ($r = .75$; Table 4). Therefore, construct validity and concurrent validity were good. Correlation was weak between "impact on finances" and BIC.

Known Groups Validity

To address known groups' validity, we examined the t test or trend test. On average, the subscale score of "impact on schedule" was 17.0 for 6 hours or less and 19.7 for more than 6 hours ($P = .04$). Likewise, the subscale of "caregiver's self-esteem" was 15.4 and 13.4 ($P = .16$), the subscale of "lack of family

Table 4. Construct and Concurrent Validity^a

Caregiver Reaction Assessment	Time-Dependent Burden	Emotional Burden	Existential Burden	Physical Burden	Service-Related Burden	Total Care Burden	BIC Total
Impact on schedule	0.75 ^b	0.36 ^c	0.38 ^c	0.62 ^b	0.14	0.52 ^b	0.66 ^b
Caregiver's self-esteem	0.22	0.66 ^b	0.54 ^b	0.09	0.47 ^b	0.35 ^d	0.52 ^b
Lack of family support	0.15	0.31 ^d	0.43 ^c	0.38 ^c	0.10	0.31 ^d	0.37 ^c
Impact on health	0.56 ^b	0.29 ^d	0.28 ^d	0.75 ^b	0.12	0.55 ^b	0.60 ^b
Impact on finances	-0.14	-0.02	0.10	0.04	-0.24	-0.02	-0.08

Abbreviation: BIC, Burden Index of Caregivers.

^a Figures show Pearson correlation coefficients. Underlined figures show items that are assumed correlations.

^b $P < .001$.

^c $P < .01$.

^d $P < .05$.

support" was 8.7 and 7.8 ($P = .41$), and the subscale score of "impact on health" was 5.3 and 5.6 ($P = .57$) for 6 hours or less and more than 6 hours, respectively. The subscale scores of "impact on finances" were 5.8 for the group whose income was less than 2 million yen, 5.2 for 2 to 4 million yen, 4.4 for 4 to 6 million yen, 3.6 for 6 to 8 million yen, 4.8 for 8 to 10 million yen, and 3.5 for 10 million yen and above ($P = .02$).

Discussion

This study confirms the reliability and validity of the CRA-J. Financial impact is a frequently reported problem, as is influence on caregivers' quality of life.³⁶⁻⁴² Therefore, the CRA, which contains a financial subscale, is thought to be useful for caregivers of cancer patients. Additionally, the CRA includes not only negative aspects of caregiving but also positive ones. Lawton et al have pointed out that it is important to comprehend both aspects. So far, few scales that measure positive and negative impact of caregiving have been tested. This is especially true in Japan because we have few suitable multidimensional scales as yet. However, the CRA-J allows multidimensional evaluation of responsiveness for interventions. Consequently, the CRA is of growing importance in clinical practice and research.

As for factor validity, we did not replicate the original results. This is due to the fact that "impact on schedule" and "impact on health" contributed to the same factor, and therefore item 18 (physical strength) was misinterpreted. We assumed that item 18 would contribute only to the "impact on health" subscale. However, it might have contributed to the "impact on schedule" and "self-esteem" subscales

as well. We believed that caregivers would think this item was intended to measure physical and emotional burden. In addition, the original scale include reversed score items. That is, in subscales that had a negative meaning, a few positive questions were included and the respondents might have been confused. We, therefore, calculated these items by reversing the scoring, for example from 0 to 5 rather than 4 to 1. We think that Japanese caregivers are not accustomed to reversed score items. Therefore, we excluded the reversed score items with cultural differences. Nijbouer et al, who validated the Dutch version of the CRA, pointed out a similar thing.³² The internal consistency of the subscales was sufficient.

Construct and concurrent validity were acceptable. The correlation between the CRA-J and BIC shows that the subscales of CRA-J strongly correlated with the supposed subscales of the BIC. The results showed that "impact on finances" weakly correlated with the BIC. The BIC has no comparable subscales, so this result is reasonable. Known groups' validity of the subscales is supported. This study calculated the Spearman's correlation coefficient between 2 subscales of the CRA-J and time spent on care per day and "impact on finances" and income, because previous studies showed inconsistent results and did not fully examine known groups validity.^{30,32,34} There are several limitations in this study. First, the number of participants was small. Second, known groups validity was not fully examined.

Conclusions

In conclusion, the CRA-J is valid and reliable. This scale is useful for caregivers of cancer patients, and

is expected to be used widely to evaluate the negative and positive aspects of caregiving. As the use of day hospices and home palliative care services become more widespread in Japan, it is recommended that these results be reconfirmed.

Acknowledgments

We thank Hiromi Ando, Fusako Ishiguchi, Hiromi Itaya, Masayo Kuramochi, Midori Hiruta, Tomie Horio, Kaoru Nishikiori, and Yuki Tanaka for carrying out this study. This research was supported by Chiyoda Kenko Kaihatsu Jigyodan.

References

1. Health, Labor and Welfare Ministry. National census. http://www.dbtk.mhlw.go.jp/toukei/data/010/2006/toukeihyou/0006087/t0135628/MC220000_001.html. Accessed January 5, 2008.
2. Japan HPC. Hospice Palliative Care Japan survey in 2006. *Hospice Palliative Care Japan Annual Conference in 2007*, Nagano; 2007:112-116.
3. Foreman LM, Hunt RW, Luke CG, Roder DM. Factors predictive of preferred place of death in the general population of South Australia. *Palliat Med*. 2006;20(4):447-453.
4. Gott M, Seymour J, Bellamy G, Clark D, Ahmedzai S. Older people's views about home as a place of care at the end of life. *Palliat Med*. 2004;18(5):460-467.
5. Thomas C, Morris SM, Clark D. Place of death: preferences among cancer patients and their carers. *Soc Sci Med*. 2004;58(12):2431-2444.
6. Goodwin DM, Higginson IJ, Myers K, Douglas H-R, Normand CE. Effectiveness of palliative day care in improving pain, symptom control, and quality of life. *J Pain Symptom Manage*. 2003;25(3):202-212.
7. Lee L. Interprofessional working in hospice day care and the patients' experience of the service. *Int J Palliat Nurs*. 2002;8(8):389-400.
8. Hopkinson JB, Hallett CE. Patients' perceptions of hospice day care: a phenomenological study. *Int J Nurs Stud*. 2001;38(1):117-125.
9. Lohfeld LH, Tschopp AS, Trevor AW, Brazil K, Krueger P. Assessing the need for and potential role of a day hospice: a qualitative study. *J Palliat Care*. 2000;16(4):5-12.
10. Spencer DJ, Daniels LE. Day hospice care—a review of the literature. *Palliat Med*. 1998;12(4):219-229.
11. Langley-Evans A, Payne S. Light-hearted death talk in a palliative day care context. *J Adv Nurs*. 1997;26(6):1091-1097.
12. Sharma K, Oliver D, Blatchford G, Higginbottom P, Khan V. Medical care in hospice day care. *J Palliat Care*. 1993;9(3):42-43.
13. Arai Y, Kudo K, Hosokawa T, Washio M, Miura H, Hisamichi S. Reliability and validity of the Japanese version of the Zarit Caregiver Burden Interview. *Psychiatry Clin Neurosci*. 1997;51(5):281-287.
14. Abe K. Reconsidering the Caregiving Stress Appraisal scale: validation and examination of its association with items used for assessing long-term care insurance in Japan. *Arch Gerontol Geriatr*. 2007;44(3):287-297.
15. Kuzuya M, Masuda Y, Hirakawa Y, et al. Falls of the elderly are associated with burden of caregivers in the community. *Int J Geriatr Psychiatry*. 2006;21(8):740-745.
16. Schreiner AS, Morimoto T, Arai Y, Zarit S. Assessing family caregiver's mental health using a statistically derived cut-off score for the Zarit Burden Interview. *Aging Mental Health*. 2006;10(2):107-111.
17. Onishi J, Suzuki Y, Umegaki H, Nakamura A, Endo H, Iguchi A. Influence of behavioral and psychological symptoms of dementia (BPSD) and environment of care on caregivers' burden. *Arch Gerontol Geriatr*. 2005;41(2):159-168.
18. Kumamoto K, Arai Y. Validation of 'personal strain' and 'role strain': subscales of the short version of the Japanese version of the Zarit Burden Interview (J-ZBI_8). *Psychiatry Clin Neurosci*. 2004;58(6):606-610.
19. Morimoto T, Schreiner AS, Asano H. Caregiver burden and health-related quality of life among Japanese stroke caregivers. *Age Ageing*. 2003;32(2):218-223.
20. Miyamoto Y, Ito H, Otsuka T, Kurita H. Caregiver burden in mobile and non-mobile demented patients: a comparative study. *Int J Geriatr Psychiatry*. 2002;17(8):765-773.
21. Arai Y, Zarit SH, Sugiura M, Washio M. Patterns of outcome of caregiving for the impaired elderly: a longitudinal study in rural Japan. *Aging Mental Health*. 2002;6(1):39-46.
22. Kim Y, Schulz R, Carver CS. Benefit-finding in the cancer caregiving experience. *Psychosom Med*. 2007;69(3):283-291.
23. Pinquart M, Sorensen S. Associations of caregiver stressors and uplifts with subjective well-being and depressive mood: a meta-analytic comparison. *Aging Mental Health*. 2004;8(5):438-449.
24. Hunt CK. Concepts in caregiver research. *J Nurs Scholarsh*. 2003;35(1):27-32.
25. Cohen CA, Colantonio A, Vernich L. Positive aspects of caregiving: rounding out the caregiver experience. *Int J Geriatr Psychiatry*. 2002;17(2):184-188.
26. Kramer BJ. Gain in the caregiving experience: where are we? What next? *Gerontologist*. 1997;37(2):218-232.

27. Langner SR. Finding meaning in caring for elderly relatives: loss and personal growth. *Holist Nurs Pract.* 1995;9(3):75-84.
28. Bachner YG, O'Rourke N, Carmel S. Psychometric properties of a modified version of the Caregiver Reaction Assessment Scale measuring caregiving and post-caregiving reactions of caregivers of cancer patients. *J Palliat Care.* 2007;23(2):80-86.
29. Grov EK, Fossa SD, Sorebo O, Dahl AA. Primary caregivers of cancer patients in the palliative phase: a path analysis of variables influencing their burden. *Soc Sci Med.* 2006;63(9):2429-2439.
30. Grov EK, Fossa SD, Tonnessen A, Dahl AA. The caregiver reaction assessment: psychometrics, and temporal stability in primary caregivers of Norwegian cancer patients in late palliative phase. *Psychooncology.* 2006;15(6):517-527.
31. Jepson C, McCorkle R, Adler D, Nuamah I, Lusk E. Effects of home care on caregivers' psychosocial status. *Image J Nurs Sch.* 1999;31(2):115-120.
32. Nijboer C, Triemstra M, Tempelaar R, Sanderman R, van den Bos GA. Measuring both negative and positive reactions to giving care to cancer patients: psychometric qualities of the Caregiver Reaction Assessment (CRA). *Soc Sci Med.* 1999;48(9):1259-1269.
33. Nijboer C, Triemstra M, Tempelaar R, Sanderman R, van den Bos GA. Determinants of caregiving experiences and mental health of partners of cancer patients. *Cancer.* 1999;86(4):577-588.
34. Given CW, Given B, Stommel M, Collins C, King S, Franklin S. The caregiver reaction assessment (CRA) for caregivers to persons with chronic physical and mental impairments. *Res Nurs Health.* 1992;15(4):271-283.
35. Miyashita M, Yamaguchi A, Kayama M, et al. Validation of the Burden Index of Caregivers (BIC), a multidimensional short care burden scale from Japan. *Health Qual Life Outcomes.* 2006;4:52.
36. Hanratty B, Holland P, Jacoby A, Whitehead M. Financial stress and strain associated with terminal cancer—a review of the evidence. *Palliat Med.* 2007;21(7):595-607.
37. Giorgi Rossi P, Beccaro M, Miccinesi G, et al. Dying of cancer in Italy: impact on family and caregiver. The Italian Survey of Dying of Cancer. *J Epidemiol Community Health.* 2007;61(6):547-554.
38. Longo CJ, Fitch M, Deber RB, Williams AP. Financial and family burden associated with cancer treatment in Ontario, Canada. *Support Care Cancer.* 2006;14(11):1077-1085.
39. Grunfeld E, Coyle D, Whelan T, et al. Family caregiver burden: results of a longitudinal study of breast cancer patients and their principal caregivers. [see comment]. *CMAJ.* 2004;170(12):1795-1801.
40. Hwang SS, Chang VT, Cogswell J, et al. Study of unmet needs in symptomatic veterans with advanced cancer: incidence, independent predictors and unmet needs outcome model. *J Pain Symptom Manage.* 2004;28(5):421-432.
41. Tilden VP, Tolle SW, Drach LL, Perrin NA. Out-of-hospital death: advance care planning, decedent symptoms, and caregiver burden. *J Am Geriatr Soc.* 2004;52(4):532-539.
42. Emanuel EJ, Fairclough DL, Slutsman J, Emanuel LL. Understanding economic and other burdens of terminal illness: the experience of patients and their caregivers. *Ann Intern Med.* 2000;132(6):451-459.

The Japan HOspice and Palliative Care Evaluation Study (J-HOPE Study): Views About Legalization of Death With Dignity and Euthanasia Among the Bereaved Whose Family Member Died at Palliative Care Units

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There has been a debate in appropriateness of legalization of death with dignity and euthanasia in Japan. To clarify views about these issues, we conducted a large nationwide study of the bereaved whose family member died at palliative care units. The percentages of 429 bereaved family members (response rate 65%) who affirmed legal authorization were 52 for death with dignity and 45 for euthanasia and who affirmed assignment

at the discretion of the physician involved were 37 for death with dignity and 38 for euthanasia. In conclusion, views about legalization of death with dignity and euthanasia among the bereaved are inconsistent. No consensus is reached as to legislation of these issues.

Keywords: palliative care; bereavement; death with dignity; euthanasia; Japan

Introduction

Following recent advances in health care technology, it is now possible to prolong the survival period of terminally ill patients. At the same time, there has been active debate on choices of treatment at the end of life in many countries. In the Netherlands and Belgium, active measures have been legally authorized for euthanasia and physician-assisted suicide for terminally ill patients. In France, withdrawal or withholding of life-prolonging measures at terminal

stages of illness has been legally permitted. In the United States, physician-assisted suicide has been authorized legally only in Oregon State.

Currently in Japan, euthanasia is strictly restricted. But withdrawal or withholding of life-prolonging measures was accepted in court judgments as if the patient was terminally ill and expressed an intention to withdraw or withhold such measures in advance. These court judgments were based on the patient's right of self-determination and limitation of the physician's duty of treatment. However, because no statute or public guideline is currently available on these topics in Japan, it has been assigned at the discretion of medical professionals whether they take such measures.

The Japanese Ministry of Health, Labor, and Welfare has strongly supported the provision of specialized palliative care services. Palliative care units (PCUs) have been covered by National Medical Insurance since 1990. The number of PCUs has dramatically increased from just 5 in 1990 to 178

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in 2007. Although the number of PCUs has been increasing, the proportion of cancer deaths covered was 6% in 2006 and 7% in 2007. More than 80% of cancer patients died in a general hospital ward. The most common type of specialized palliative care service in Japan is therefore the PCUs.

It has been reported that among the patients admitted to PCUs, 10% desired euthanasia and the reasons for these desires were (1) general malaise, (2) concerns about future distress, (3) burden on others, and (4) pain.¹ According to a survey of medical professionals belonging to the Japanese Society for Palliative Medicine, more than half of these physicians had been asked by patients to hasten their death.² These previous survey results indicate that some members of the general public and patients receiving palliative care in Japan desire euthanasia.

To clarify views about legalization of death with dignity and euthanasia, we conducted a large nationwide study of the bereaved whose family member died at PCUs.

Methods

Participants

In September 2005, the executive office for this study mailed a protocol explaining the objectives of the study of bereaved families and an informed consent form to 153 PCUs across the country. One hundred PCUs (65.4%) consented to the study. We asked these PCUs to furnish the executive office with a list of 80 family members who satisfied the inclusion criteria and met none of the exclusion criteria (given below) and who had experienced the death of a family member between November 2004 and October 2006. The participants of this study were part of the bereaved for the Japan HOspice and Palliative care Evaluation study (the J-HOPE study) held for quality assurance, evaluation, and improvement.³

The inclusion criteria were as follows: (1) patient died at a PCU or at home, (2) patient was aged ≥ 20 years, and (3) bereaved family member was aged ≥ 20 years. The exclusion criteria were as follows: (1) could not identify the bereaved family member's address, (2) participant would have suffered serious psychological distress as determined by the primary physician, and (3) participant was incapable of replying to a self-reported questionnaire.

Each bereaved family member enrolled in the study was asked to answer both a common questionnaire

and questions pertaining to 12 research topics. Bereaved family members were divided into 12 groups and were asked to answer 1 of the 12 different questionnaires (containing common questions and questions specific to a given research topic) corresponding to the 12 groups. The study pertained to 1 of the 12 research topics. A questionnaire carrying common questions and questions specific to this research topic was sent to 661 bereaved family members. Valid responses were collected from 429 bereaved family members (65%). Ethical and scientific validity of the study was checked and authorized in advance by the ethics committee of each participating PCU and the ethics committee of the Graduate School of Medicine, The University of Tokyo, in which the executive office for the study was located.

Survey

Death with dignity. Death with dignity was defined as "discontinuation of treatment which is aimed at prolonging the life of the patient but is useless to the patient, on the basis of the desire of the patient and his/her family members." The bereaved were asked to select 1 of the 3 choices regarding death with dignity: (1) death with dignity should be authorized legally; (2) whether to take measures for death with dignity should be assigned at the discretion of the physician involved; and (3) death with dignity should be banned legally.

Euthanasia. Euthanasia was defined as "administration of drugs causing death of the patient by a physician, on the basis of the explicit desire of the patient, where the patient is suffering from severe pain and there is no means to relieve the patient of the pain." The bereaved were asked to select 1 of the 3 choices regarding euthanasia: (1) euthanasia should be authorized legally; (2) whether to take measures for euthanasia should be assigned at the discretion of the physician involved; and (3) euthanasia should be banned legally.

Background variables. Each subject was additionally asked about the following background variables: (1) gender of the patient, (2) age of the patient, (3) period of stay in the PCU, (4) primary site of cancer, (5) gender of the bereaved family member, (6) age of the

bereaved family member, (7) relationship to the patient, (8) health status of the bereaved family member during care of the patient, (9) frequency of attendance at the PCU, (10) presence/absence of any other person having cared of the patient, and (11) cost of care billed during the 1-month period before death. The health status of the bereaved family member during care of the patient was rated on a 2-category scale: (1) good health status (family members answering "good" or "fair") and (2) poor health status (family members answering "bad" or "quite bad").

Statistical Analysis

Fisher's exact test was used for comparison of each parameter. Data were analyzed using the statistical computer program SAS (SAS Institute: version 9.1, Cary, NC).

Results

Demographic Data

Table 1 summarizes the demographic data for the 429 bereaved family members studied. There were 118 men (28%) and 311 women (72%), with a mean age of 59 years. The most frequent relationship to the patient was spouse (n = 215, 51%), followed by child (n = 134, 32%) and brother/sister (n = 28, 7%).

Death With Dignity (Withdrawal of Life-prolonging Treatment)

To the question about death with dignity, 52% (n = 223) chose "death with dignity should be authorized legally," 37% (n = 160) chose "whether or not to take measures for death with dignity should be assigned at the discretion of the physician involved," 3% (n = 12) chose "death with dignity should be banned legally," and 8% (n = 34) gave no answer.

Demographic data significantly affecting the answer to the question about death with dignity were the age of the bereaved family member and the relationship to the patient (Table 2). The answer "death with dignity should be authorized legally" was chosen significantly more by the bereaved younger than 60 years ($P = .001$), and the bereaved whose relationship to the patient was not the spouse ($P = .003$).

Table 1. Backgrounds of the Bereaved Family Members

Patients	
Gender	
Male	58.0% (n = 249)
Female	42.0% (n = 180)
Age (years)	70.1 ± 11.6
Period of stay in the palliative care unit (days)	43.4 ± 55.4
Primary site of cancer	
Lung	21.0% (n = 90)
Liver/biliary tract/pancreas	17.9% (n = 77)
Esophagus/stomach	16.6% (n = 71)
Colon	11.9% (n = 51)
Prostate/kidney/bladder	7.9% (n = 34)
Breast	5.6% (n = 24)
Uterus/ovary	4.7% (n = 20)
Head/neck	4.0% (n = 17)
Others	10.3% (n = 44)
The bereaved family members	
Gender	
Male	27.5% (n = 118)
Female	72.5% (n = 311)
Age (years)	59.4 ± 12.0
Relationship to the patient	
Spouse	50.5% (n = 215)
Child	31.5% (n = 134)
Siblings	6.6% (n = 28)
Sons/daughters-in-law	5.6% (n = 24)
Parents	1.4% (n = 6)
Others	4.5% (n = 19)
Health status of during care of the patient	
Good	75.3% (n = 318)
Bad	24.6% (n = 104)
Frequency of attending the patient	
4~7 d/wk	83.7% (n = 355)
0~3 d/wk	16.3% (n = 69)
Presence/absence of any other person having cared of the patient	
Presence	67.6% (n = 288)
Absence	32.4% (n = 138)
Cost of care billed during 1-month period before death (yen)	
>200 000/month	58.2% (n = 241)
<200 000/month	41.8% (n = 173)

Euthanasia

To the question about euthanasia, 45% (n = 192) chose "euthanasia should be authorized legally," 38% (n = 161) chose "whether or not to take measures for euthanasia should be assigned at the discretion of the physician involved," 6% (n = 26) chose "euthanasia should be banned legally," and 12% (n = 50) gave no answer.

Table 2. Views on Death With Dignity

	Should be Clearly Authorized by the Law		Should be Clearly Banned by the Law		Should be Assigned at the Discretion or the Physician Involved		
	n	%	n	%	n	%	P Values
Patient age (years)							
>60	186	58	10	3	125	39	.450
<60	37	50	2	3	35	47	
Patient gender							
Male	130	57	9	4	88	39	.370
Female	93	55	3	2	72	43	
Length of hospital stay (days)							
>40	77	55	1	1	63	45	.073
<40	146	57	11	4	97	38	
Age of the bereaved family member (years)							
>60	92	47	9	5	95	48	.001
<60	130	66	3	2	63	32	
Gender of the bereaved family member							
Male	80	54	2	2	49	44	.011
Female	163	58	10	4	108	38	
Health condition of the bereaved family member during the patient hospitalization							
Good, not so bad	176	59	9	3	112	38	.205
Not good, seriously bad	47	51	2	2	44	47	
Relationship to the patient							
Spouse	99	50	10	5	91	48	.003
Others	124	64	2	1	67	35	
Frequency of attending the patient							
Every day, 4-6 d/wk	177	54	12	4	138	42	.093
1-3 d/wk, none	44	67	0	0	22	33	
Presence/absence of any others person having cared of the patient							
Presence	154	58	7	3	106	40	.674
Absence	69	55	5	4	52	41	
Cost of care billed the last month (yen)							
>200 000	129	59	8	4	83	38	.340
<200 000	85	53	4	2	72	45	

Demographic data significantly affecting the answer to the question about euthanasia were the age of the bereaved family member and the relationship to the patient (Table 3). The answer "euthanasia should be authorized legally" was chosen significantly more by the bereaved younger than 60 years ($P = .001$) and the bereaved whose relationship to the patient was not the spouse ($P = .003$).

The percentages of the bereaved choosing "death with dignity" were significantly different from those choosing "euthanasia."

Discussion

According to the survey conducted in 2003 by the Ministry of Health, Labor, and Welfare, 13% of the

general public stated that they want euthanasia if they are terminally ill and suffer from pain.⁴ Furthermore, 46% of the general public prefers euthanasia as a means of treating severe refractory physical distress, and those who prefer euthanasia tend to regard "control over the future" as important for a good death.⁵

The advanced legal systems regarding euthanasia in several Western countries have been attributed to the following factors: (1) improved awareness, attaching importance to the patient's autonomy and self-determination and (2) an increase in the percentage of individuals who desire control of the end of their life, instead of following a natural course.⁶⁻⁹

In past surveys of the awareness of patients and their family members, major reasons for desiring euthanasia are psychological, social, or spiritual

Table 3. Views on Euthanasia

	Should be Clearly Authorized by the Law		Should be Clearly Banned by the Law		Should be Assigned at the Discretion or the Physician Involved		P Values
	n	%	n	%	n	%	
Patient age (years)							
>60	161	52	19	6	128	42	.302
<60	31	44	7	10	33	46	
Patient gender							
Male	105	49	16	7	94	44	.706
Female	87	53	10	6	67	41	
Length of hospital stay (days)							
>40	70	51	4	3	63	46	.057
<40	122	50	22	9	98	40	
Age of the bereaved family member (years)							
>60	83	44	8	4	97	52	.001
<60	108	57	18	10	62	33	
Gender of the bereaved family member							
Male	57	52	8	7	44	40	.905
Female	135	51	18	7	114	43	
Health condition of the bereaved family member during the patient hospitalization							
Good, not so bad	145	50	15	5	128	44	.063
Not good, seriously bad	47	54	10	11	30	34	
Relationship to the patient							
Spouse	82	43	12	6	97	51	.003
Others	110	59	14	8	62	33	
Frequency of attending the patient							
Every day, 4-6 d/wk	62	61	7	7	33	32	.051
1-3 d/wk, none	129	47	19	7	125	46	
Presence/absence of any others person having cared of the patient							
Presence	136	53	20	8	102	40	.278
Absence	56	47	6	5	57	48	
Cost of care billed the last month (yen)							
>200 000	109	52	16	8	86	41	.711
<200 000	75	48	10	6	70	45	

factors rather than physical pain.^{1,10-12} In the Netherlands, where euthanasia has been authorized legally, euthanasia is permitted in cases where all kinds of suffering (including nonphysical suffering) are difficult to alleviate and most physicians believe that euthanasia could be appropriate in some cases.¹³ But the number of cases where euthanasia or physician-assisted suicide was implemented in the Netherlands has been decreasing in recent years.¹⁴

Regarding a difference in awareness between the general public and the medical professionals, it has been reported that members of the general public (including patients and bereaved family members) often affirm euthanasia, while the medical professionals often deny euthanasia.¹⁵⁻¹⁷ According to a

survey conducted in Japan, the percentage of physicians and nurses who affirmed euthanasia as a means of pain relief was about 1% and none of the physicians involved in palliative care affirmed it.¹⁸ A discrepancy in awareness about euthanasia between the general public and the medical professionals tends to be commonly seen in many countries.^{17,19,20}

In previous surveys of the general public about death with dignity (discontinuation of life-prolonging treatment) in Japan, 74% to 76% answered: "If I am at a terminal stage of cancer, I want to discontinue treatment simply aimed at life prolongation."⁴ According to an opinion poll in 2007, 89% of the respondents desired no life-prolonging measure (eg, treatment with a ventilator) if only life-prolonging

treatment is available, and 80% affirmed the necessity of legislation about discontinuation of life-prolonging treatment. Many members of the general public expressed a view affirming death with dignity, and more than 80% of medical professionals affirmed it.²¹ However, in response to the question about death with dignity in this study, 52% of the bereaved affirmed the legal authorization as many as 37% of the bereaved affirmed the assignment at the discretion of the physician involved. Thus, there are still controversial issues about death with dignity in Japan.

The percentages of the bereaved who affirmed legal authorization of death with dignity and euthanasia were significantly higher among those younger than 60 years and those whose relationship to the patient was other than a spouse. It was previously reported that younger individuals tend to attach more importance to the patient's autonomy²² and more often tend to provide positive responses to physician-assisted suicide and euthanasia.^{7,23} The results of this study endorse these previous findings. In most previous surveys, the gender of family members was found to have no significant impact on views concerning suicide or euthanasia for terminally ill persons.^{7,8,23} This previous finding also coincides with this study.

There are several surveys of Japanese general public for views about discontinuation of life-prolonging treatment and euthanasia, the distinction of our study is that the bereaved whose family member died at PCUs were surveyed. We thought it important that views about legalization of death with dignity and euthanasia among those who experienced specialized palliative care service were surveyed in Japan.

A limitation of this study is that the percentage of valid responses was not a high rate (65%). In a past survey of the Canadian general public, respondents who failed to distinguish between euthanasia and treatment withdrawal or withholding treatment in hypothetical scenarios were more likely to support euthanasia.²⁴ Inadequate distinction between death with dignity and euthanasia in the awareness of individuals may be one of the factors explaining the high percentage of the bereaved who affirmed legal authorization of euthanasia in this study.

In this study, the percentage of the bereaved who affirmed legal authorization was 52 for death with dignity and 45 for euthanasia. The percentage of the bereaved who affirmed assignment at the discretion of the physician involved was 37 for death with dignity

and 38 for euthanasia. Thus, views about legalization of death with dignity and euthanasia among the bereaved is inconsistent. No consensus is reached as to legislation of these issues.

Acknowledgments

This study was supported by Grant-in-Aid from the Japan Hospice Palliative Care Foundation.

References

1. Morita T, Sakaguchi Y, Hirai K, Tsuneto S, Shima Y. Desire for death and requests to hasten death of Japanese terminally ill cancer patients receiving specialized inpatient palliative care. *J Pain Symptom Manage*. 2004;27:44-52.
2. Asai A, Ohnishi M, Nagata SK, Tanida N, Yamazaki Y. Doctors' and nurses' attitudes towards and experiences of voluntary euthanasia: survey of members of the Japanese Association of Palliative Medicine. *J Med Ethics*. 2001;27:324-330.
3. Miyashita M, Morita T, Tsuneto S, Sato K, Shima Y. The Japan HOspice and Palliative Care Evaluation study (J-HOPE study): study design and characteristics of participating institutions. *Am J Hosp Palliat Care*. 2008;25:223-232.
4. Division of Public Policy. Report of a Survey of the Japanese General Public Regarding Their Preferences in Regard to Terminal Care. Tokyo: Ministry of Health and Welfare; 1998, 2003.
5. Sanjo M, Miyashita M, Morita T, et al. Preferences regarding end-of-life cancer care and associations with good-death concepts: a population-based survey in Japan. *Ann Oncol*. 2007;18:1539-1547.
6. Cohen J, Marcoux I, Bilsen J, Deboosere P, van der Wal G, Deliens L. Trends in acceptance of euthanasia among the general public in 12 European countries (1981-1999). *Eur J Public Health*. 2006;16:663-669.
7. Cohen J, Marcoux I, Bilsen J, Deboosere P, van der Wal G, Deliens L. European public acceptance of euthanasia: socio-demographic and cultural factors associated with the acceptance of euthanasia in 33 European countries. *Soc Sci Med*. 2006;63:743-756.
8. DeCesare MA. Public attitudes toward euthanasia and suicide for terminally ill persons: 1977 and 1996. *Soc Biol*. 2000;47:264-276.
9. Woods S. Respect for persons, autonomy and palliative care. *Med Health Care Philos*. 2005;8:243-253.
10. Hudson PI., Kristjanson LJ, Ashby M, et al. Desire for hastened death in patients with advanced disease and the

- evidence base of clinical guidelines: a systematic review. *Palliat Med.* 2006;20:693-701.
11. Johansen S, Hølen JC, Kaasa S, Loge HJ, Materstvedt LJ. Attitudes towards, and wishes for, euthanasia in advanced cancer patients at a palliative medicine unit. *Palliat Med.* 2005;19:454-460.
 12. Suarez-Almazor ME, Newman C, Hanson J, Bruera E. Attitudes of terminally ill cancer patients about euthanasia and assisted suicide: predominance of psychosocial determinants and beliefs over symptom distress and subsequent survival. *J Clin Oncol.* 2002;20:2134-2141.
 13. Georges JJ, Onwuteaka-Philipsen BD, van der Heide A, van der Wal G, van der Maas PJ. Physicians' opinions on palliative care and euthanasia in the Netherlands. *J Palliat Med.* 2006;9:1137-1144.
 14. van der Heide A, Onwuteaka-Philipsen BD, Rurup ML, et al. End-of-life practices in the Netherlands under the Euthanasia Act. *N Engl J Med.* 2007;356:1957-1965.
 15. O'Neill C, Feenan D, Hughes C, McAlister DA. Physician and family assisted suicide: results from a study of public attitudes in Britain. *Soc Sci Med.* 2003;57:721-731.
 16. Rynänen OP, Myllykangas M, Viren M, Heino H. Attitudes towards euthanasia among physicians, nurses and the general public in Finland. *Public Health.* 2002;116: 322-331.
 17. Chong AM, Fok SY. Attitudes toward euthanasia in Hong Kong—a comparison between physicians and the general public. *Death Stud.* 2005;29:29-54.
 18. Miyashita M, Hashimoto S, Kawa M. Attitudes towards terminal care among the general population and medical practitioners in Japan [in Japanese]. *Nippon Koshu-Eisei Zasshi.* 1999;46:391-401.
 19. Emanuel EJ, Fairclough DL, Daniels ER, Clarridge BR. Euthanasia and physician-assisted suicide: attitudes and experiences of oncology patients, oncologists, and the public. *Lancet.* 1996;347:1805-1810.
 20. Suarez-Almazor ME, Belzile M, Bruera E. Euthanasia and physician-assisted suicide: a comparative survey of physicians, terminally ill cancer patients, and the general population. *J Clin Oncol.* 1997;15:418-427.
 21. Hiraoka K, Yamauchi K, Ikushima M, Iizuka Y, Takada I, Takei I. Differences in awareness of euthanasia and death with dignity among patients, physicians and nurses. *Kango Sogo.* 2003;34:72.
 22. Ruhnke GW, Wilson SR, Akamatsu T, et al. Ethical decision making and patient autonomy: a comparison of physicians and patients in Japan and the United States. *Chest.* 2000;118:1172-1182.
 23. Emanuel EJ, Fairclough DL, Emanuel LL. Attitudes and desires related to euthanasia and physician-assisted suicide among terminally ill patients and their caregivers. *JAMA.* 2000;284:2460-2468.
 24. Marcoux I, Mishara BL, Durand C. Confusion between euthanasia and other end-of-life decisions: influences on public opinion poll results. *Can J Public Health.* 2007;98: 235-239.

Prospective Evaluation of Transition to Specialized Home Palliative Care in Japan

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The aim of this study was to clarify patients' characteristics and the level of symptom management in the transition to specialized home palliative care, and to examine prospectively real-time evaluation of both terminal cancer patients and their families. This study was conducted at one of the largest institutions offering specialized home palliative care in Japan. We asked both the patient's and the family's health status at the initial assessment and 2 weeks later. One hundred sets of patients and their families were included in this

study. Regarding patient characteristics at the time of referral to the specialized home palliative care service, patients referred from outpatient settings had more severe physical symptoms than patients referred from inpatient settings. The specialized home palliative care service could contribute to patients' symptom and families' psychosocial status.

Keywords: terminally ill; cancer; palliative care; home; prospective study

Introduction

A shift to community-based rather than hospital-based palliative care programs has been seen around the world.¹

In Japan, cancer is the leading cause of death. Palliative care units, which provide specialized palliative care service within inpatient care systems, have gained the support of the Ministry of Health, Labor and Welfare, and have spread throughout the country. However, improvement of support in the community for terminal cancer patients has been slow, and the availability of interdisciplinary specialized home palliative care (SHPC) services and outpatient palliative care services are very limited.^{2,3}

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As a practical matter, in Japan, the proportion of cancer patients who died at home was only 6%.⁴ In addition, many people regard a home death as unrealizable, although those surveyed expressed preference for a home care setting as their preferred place of end-of-life care.⁵ Therefore, enhancement of palliative care at home for cancer patients is a priority in Japan.

To improve palliative care at home, it is necessary to demonstrate that SHPC can have positive impact on terminal cancer patients and their families. In general, the impact of SHPC service was more positive than negative in studies of western countries, in particular, indicating improved care satisfaction and pain and other symptom control.⁶ However, transition to palliative care and living at home are still considered difficult processes,^{7,8} and to date, there have been no studies specifically dealing with experiences of transition from the hospital or outpatient setting to SHPC in Japanese cancer care. Additionally, the need for prospective study was pointed out from the viewpoint both patients and families as a future issue.⁹

The aim of this study was to clarify patients' characteristics and the level of symptom management in

the transition to SHPC, and to examine prospectively real-time evaluation of both patients and families.

Patients and Methods

This study was a prospective study conducted at one of the largest institutions (Okabe Clinic, in Miyagi Prefecture) offering SHPC in Japan.

Setting

The Japanese medical system does not necessarily provide for home visits by the family physician during home care for patients living at home. Typically, the form of home care is based primarily on collaboration between home care nurses and the family physician and/or the hospital physician.³ However, in one organization, mainly the SHPC service of Okabe Clinic is provided by multiprofessionals and offers comprehensive services to terminal cancer patients. The basic members of the SHPC service comprise palliative care physicians, nurses, caseworkers, and so on. If the SHPC service requires other care specialists, inpatient care, day care, and so on, they are made available in regional networks. In principle, all patients were continuously followed after the initial assessment by at least a physician and a nurse. Each patient was visited at least once per week by a physician and at least 3 times per week by a nurse. If required, a visit was also carried out every day.

Participants

The participants were terminal cancer patients and their families who had been referred to the SHPC service.

The inclusion criteria were as follows: the patient (a) was aged 20 years and more; (b) was able to participate in a brief interview; (c) did not suffer from a severe mental or cognitive disorder, as determined by the physician; and (d) the patient and his/her family were living together. When a patient did not meet the inclusion criteria, we investigated only the family. A written informed consent was obtained from each patient and his/her family. This study was approved by the Institutional Review Board of Okabe Clinic.

Design and Procedures

This study was conducted via a prospective questionnaire survey. We consecutively enrolled patients and

their families as potential participants after they had been newly referred to the SHPC service. Within 72 hours after a medical examination by the primary responsible physicians, the researchers fully explained to each patient and family the purpose of the study, both orally and by providing relevant reading material, at the patient's house. After obtaining written consent, we recorded both the patient's and the family's health status on a structured data collection sheet at the initial assessment and, then, 2 weeks later, through home visit interviews and chart reviews. Patients and their families were enrolled between January 2004 and January 2005 and followed-up on until February 2005.

Measurements

Quality of life: Self-reported health status by patients (EQ-5D). Data was collected by conducting face to face interviews. EQ-5D is a standardized instrument used to measure health outcomes and is applicable to a wide range of health conditions and treatments.¹⁰ The EQ-5D descriptive system consists of 5 dimensions: mobility, self-care, usual activity, pain/discomfort, and anxiety/depression. Each dimension has 3 levels from 1 (no problem) to 3 (extreme problem).

Patient symptoms assessed by medical professionals. The severity of pain, numbness, fatigue, dyspnea, cough, sputum, nausea, vomiting, abdominal swelling, diarrhea, dry mouth, somnolence, and insomnia was rated by the medical members of the SHPC service using the Japanese version of the Schedule for Team Assessment Scale (STAS-J).¹¹ We rated symptom levels as 0 (none), 1 (mild), 2 (moderate), 3 (severe), or 4 (extreme). Appetite loss, constipation, and fever were clinically rated as none (0), mild (1), and moderate to severe (2). This evaluation schedule was developed in a nation-wide project to establish a standard assessment data sheet in palliative care settings, in which more than 20 palliative care units participated.

Families' health status and families' perception of patients' health status. Data was collected by conducting face to face interviews. We asked the families about their anxiety regarding care at home, and their sleep situation and physical status. Anxiety regarding care at home was rated on a 5-point Likert scale ranging from no anxiety at all to constant anxiety, and the sleep situation was recorded according to the reply to a question about the frequency of night-time awakening for patient care purposes using a 5-step scale ranging from never to 5 times

or more per night. Physical status was scored from 0 (very poor status) to 10 (very good status).

In addition, we asked the families about their perception of patients' health status. Patients' physical and psychological status was respectively rated on a 5-point Likert scale ranging from no pain at all to constant pain.

Other information. We collected data on patient and family characteristics, such as age, gender, patient's tumor site, and Performance Status (ECOG) using chart reviews.

Analyses

Descriptive statistics were calculated for the study sample, and we compared patient and family characteristics and patients' symptoms at the initial assessment according to the care setting before the start of the SHPC service. To compare each group we used the Wilcoxon rank sum test, Student *t* test, the Chi-square test and Fisher exact test, where appropriate.

We also compared patients' and families' evaluations between the initial assessment and an assessment 2 weeks later (day 14). The Wilcoxon signed-ranks test was performed for comparisons between these 2 occasions.

All analyses were conducted using the SAS statistical software package version 9.1. The significance level was set at $P < .05$ (2-tailed).

Results

One hundred and forty-nine patients started to receive the SHPC service during the study period, and 100 sets of patients and their families were included in this study. The reasons for exclusion were as follows: the patient had a serious medical condition ($n = 19$); the patient had a severe mental or cognitive disorder ($n = 13$); the patient was living alone ($n = 11$); and other reasons ($n = 6$).

Patient and Family Characteristics in Transition to the SHPC Service

Table 1 summarizes the characteristics of participants by care setting before the start of the SHPC service. Forty-five patients were referred from outpatient settings and 55 patients were referred from inpatient settings. Only 3 patients from the outpatient settings and 3 patients from inpatient settings received a specialized palliative care service before

referral. Patients had any of a variety of primary sites, and many patients' performance status was ≥ 3 . A comparison showed no significant differences between patients from outpatient settings and patients from inpatient settings.

Table 2 demonstrates patient symptoms by care setting before the start of the SHPC service at initial assessment. Patients from the outpatient setting suffered from more serious pain ($P = .03$), fatigue ($P = .02$), sputum ($P = .04$), dry mouth ($P = .03$), and appetite loss ($P = .02$) than patients from the inpatient setting. Similarly, the number of moderate to extreme symptoms was significantly more frequent in patients from the outpatient setting than in patients from the inpatient setting ($P = .02$).

Change in the Patients' Quality of Life and Symptoms

Table 3 shows changes in the patients' quality of life during the 2-week period. Responses were obtained from 56 patients. There were significant deteriorations in self-reported health status scores for mobility ($P < .001$) and self-care ($P = .01$). There were no significant deteriorations regarding the scores for pain/discomfort and anxiety/depression.

Table 4 summarizes the changes in patient symptom severity assessed by medical professionals during the 2-week period. The responses were obtained from 74 patients. There were significant improvements in symptom scores of pain ($P = .02$), appetite loss ($P = .001$), and constipation ($P < .001$). Similarly, the number of moderate to extreme symptoms decreased significantly ($P = .01$). However, no significant improvement was observed in symptom score for dry mouth ($P = .003$).

Change in the Families' Health Status and Families' Perception of Patients' Health Status

Table 5 shows changes in the families' experiences with the SHPC service during the 2-week period. The responses were obtained from 74 families. There was a significant improvement in anxiety regarding care at home ($P = .002$). However, there were significant deteriorations in the frequency of night-time awakening for patient care ($P < .001$) and in the physical status ($P = .01$). The families' perception

Table 1. Characteristics of Participants by Care Setting Before the Start of Specialized Home Palliative Care (SHPC) Service

	Outpatient Settings		Inpatient Settings		P Value
	n = 45	(100%)	n = 55	(100%)	
Patient characteristics					
Age (years, mean \pm SD)	75.0 \pm 10.8		73.3 \pm 9.6		.39 ^a
Gender					
Female	23	(51)	22	(40)	.27 ^b
Male	22	(49)	33	(60)	
Anti-neoplasm medical treatment					
End/untreated	39	(87)	49	(89)	.71 ^b
Under medical treatment	6	(13)	6	(11)	
Primary site					
Lung	10	(22)	14	(25)	.47 ^c
Stomach	3	(7)	7	(13)	
Esophagus	0	(0)	2	(4)	
Colorectal	6	(13)	5	(9)	
Liver	3	(7)	8	(15)	
Pancreas	4	(9)	1	(2)	
Urological	4	(9)	5	(9)	
Breast	2	(4)	1	(2)	
Brain	4	(9)	1	(2)	
Unknown	6	(13)	5	(9)	
Others	3	(7)	6	(11)	
Performance status					
1	2	(4)	2	(4)	0.87 ^d
2	6	(13)	7	(13)	
3	23	(51)	29	(53)	
4	14	(31)	17	(31)	
Use of specialized palliative care service^e					
Presence	3	(7)	3	(5)	1.00 ^c
Absence	42	(93)	52	(95)	
Family characteristics					
Age (years, mean \pm SD)	62.4 \pm 13.0		59.5 \pm 12.3		0.27 ^a
Gender					
Female	39	(87)	48	(87)	0.93 ^b
Male	6	(13)	7	(13)	
Relationship with patient					
Spouse	21	(47)	32	(58)	0.40 ^c
Child	12	(27)	12	(22)	
Parent	2	(4)	0	(0)	
Child's spouse	10	(22)	11	(20)	
Number living together (n, mean \pm SD)	2.7 \pm 1.9		2.7 \pm 1.8		0.97 ^a

^a Student *t* test.^b Chi-square test.^c Fisher's exact test.^d Wilcoxon rank sum test.^e Use of specialized palliative care service, such as Palliative Care Unit and Hospital-based Palliative Care Team.

of patients' physical and psychological status did not change significantly.

Discussion

We clarified the real-time evaluations of 100 sets of consecutive terminal cancer patients and their

families referred to a SHPC service in Japanese cancer care settings. In Japan, very few attempts have been made at such observation.

Our participants no longer benefited from tumor-directed therapy and had been given a diagnosis of terminal cancer. Many patients' performance status were poor at the time of starting the SHPC

Table 2. Patient Symptoms by Care Setting Before the Start of Specialized Home Palliative Care (SHPC) Service at Initial Assessment

	Outpatient Settings (n = 45) Mean ± SD	Inpatient Settings (n = 55) Mean ± SD	P Value ^a
Pain	1.7 ± 1.2	1.2 ± 1.0	.03
Numbness	0.2 ± 0.8	0.4 ± 0.8	.11
Fatigue	1.9 ± 1.0	1.4 ± 1.0	.02
Dyspnea	0.5 ± 0.9	0.4 ± 0.8	.73
Cough	0.5 ± 0.8	0.3 ± 0.7	.18
Sputum	0.6 ± 0.9	0.4 ± 0.9	.04
Nausea	0.3 ± 0.7	0.5 ± 0.8	.07
Vomiting	0.1 ± 0.4	0.1 ± 0.5	.50
Abdominal swelling	1.1 ± 1.1	1.1 ± 1.0	.88
Dry mouth	1.1 ± 1.0	0.7 ± 0.8	.03
Diarrhea	0.1 ± 0.3	0.2 ± 0.5	.16
Somnolence	0.7 ± 0.9	0.5 ± 0.8	.26
Insomnia	0.8 ± 1.0	0.7 ± 0.9	.99
Appetite loss ^b	1.5 ± 0.7	1.2 ± 0.7	.02
Constipation ^b	1.5 ± 0.9	1.3 ± 0.9	.21
Fever ^b	0.1 ± 0.5	0.2 ± 0.5	.56
Number of moderate to extreme symptoms ^c	4.4 ± 2.2	3.3 ± 2.4	.02

^a Wilcoxon rank sum test.^b Appetite loss, constipation and fever; none (0) to moderate/severe (2), other symptoms; none (0) to extreme (4); Schedule for Team Assessment Scale.^c Number of moderate-to-extreme symptoms: minimum (0) to max (16).

service. Also, most patients experienced multiple moderate-to-severe symptoms. Regarding patient characteristics at the time of referral to the SHPC service, patients referred from outpatient settings had more severe physical symptoms than patients referred from inpatient settings, despite the lack of difference in the patients' backgrounds. Those findings suggest the insufficiency of symptom management for patients in outpatient settings. Patients in outpatient settings may experience barriers to effective symptom management that are not faced by patients in inpatient settings.^{12,13} Most of our participants had little contact with a specialized palliative care service until they were referred to the SHPC service. According to Morita et al,¹⁴ in Japan, the timing of referrals to palliative care units is late or very late from the family's perspective. However, the current status nationwide of SHPC service and outpatient setting is not clear. It is necessary to ensure palliative care follow-up in the outpatient setting, and the transition to SHPC should be done before the suffering of the patient and family increases.

Table 3. Change in Patients' Quality of Life During the 2-week Period

	Initial Assessment ^a n (100%)	Day 14 n (100%)	P Value ^b
Self reported health status (EQ-5D)			
Mobility (n = 56)			
No problems	16 (29)	6 (11)	<.001
Some problems	31 (55)	34 (61)	
Extreme problems	9 (16)	16 (29)	
Self-care (n = 56)			
No problems	21 (38)	13 (23)	.01
Some problems	23 (41)	24 (43)	
Extreme problems	12 (21)	19 (34)	
Usual activities (n = 56)			
No problems	4 (7)	3 (5)	.66
Some problems	14 (25)	13 (23)	
Extreme problems	38 (68)	40 (71)	
Pain/discomfort (n = 56)			
No problems	14 (25)	20 (36)	.07
Moderate problems	28 (50)	27 (48)	
Extreme problems	14 (25)	9 (16)	
Anxiety/depression (n = 55)			
No problems	35 (63)	32 (58)	1.00
Moderate problems	13 (23)	17 (31)	
Extreme problems	8 (14)	6 (11)	

^a Within 72 hours of admission.^b Wilcoxon signed-ranks test.**Table 4. Change in Patient Symptom Severity Assessed by Medical Professionals During the 2-week Period (n = 74)**

	Initial Assessment Mean ± SD	Day 14 Mean ± SD	P Value ^a
Pain	1.5 ± 1.2	1.3 ± 0.9	.02
Numbness	0.3 ± 0.8	0.3 ± 0.7	.43
Fatigue	1.6 ± 1	1.7 ± 1	.20
Dyspnea	0.4 ± 0.8	0.4 ± 0.8	1.00
Cough	0.4 ± 0.7	0.4 ± 0.6	.80
Sputum	0.5 ± 0.8	0.5 ± 0.9	.46
Nausea	0.5 ± 0.8	0.4 ± 0.8	.99
Vomiting	0.1 ± 0.5	0.3 ± 0.7	.09
Abdominal swelling	1.1 ± 1.1	1.1 ± 0.9	.67
Dry mouth	0.8 ± 0.9	1.1 ± 0.9	.003
Diarrhea	0.1 ± 0.3	0.1 ± 0.4	1.00
Somnolence	0.6 ± 0.9	0.7 ± 0.8	.35
Insomnia	0.7 ± 1	0.8 ± 1.1	.66
Appetite loss	1.3 ± 0.7	1.1 ± 0.6	.001
Constipation	1.4 ± 0.8	1 ± 0.6	<.001
Fever	0.1 ± 0.4	0.1 ± 0.4	1.00
Number of moderate to extreme symptoms	3.7 ± 2.4	3.1 ± 2.4	.01

^a Wilcoxon signed-ranks test.

Table 5. Change in Families' Health Status and Families' Perception of Patients' Health Status During the 2-week Period

	Initial Assessment		Day 14		P Value ^a
	n	(100%)	n	(100%)	
Families' health status					
Anxiety regarding care at home (n = 71)					
Not felt at all	1	(1)	3	(4)	.002
Rarely feels	21	(30)	31	(44)	
Sometimes feels	29	(41)	25	(35)	
Often feels	7	(10)	9	(13)	
Always feels	13	(18)	3	(4)	
The frequency of night-time awakening for patient care (n = 74)					
Never	34	(46)	16	(22)	<.001
Occasionally	19	(26)	17	(23)	
1-2 times per night	6	(8)	19	(26)	
3-4 times per night	12	(16)	14	(19)	
5 times or more per night	3	(4)	8	(11)	
Physical status (n = 68) ^b					
Mean ± SD	6.3 ± 1.8		5.7 ± 1.7		.01
Median (range)	6 (2-10)		6 (1-10)		
Families' perception of patients' health status					
Patients' physical status (n = 71)					
No pain	1	(1)	0	(0)	.62
Hardly painful	18	(25)	15	(21)	
Sometimes painful	30	(42)	31	(44)	
Often painful	11	(15)	21	(30)	
Always painful	11	(15)	4	(6)	
Patients' psychological status (n = 71)					
No pain	1	(1)	0	(0)	1.00
Hardly painful	18	(25)	20	(28)	
Sometimes painful	30	(42)	32	(45)	
Often painful	14	(20)	15	(21)	
Always painful	8	(11)	4	(6)	

^a Wilcoxon signed -ranks test.^b Physical status; from 0 points (very poor status) to 10 points (very good status).

The change in quality of life of the patients assessed using the EQ-5D questionnaire varied among the different domains. The scores for mobility and self-care other than usual activities deteriorated significantly during the 2-week period. The patients were aware of the rapid decline of their own functional status. The scores for pain/discomfort and anxiety/depression remained stable at the second evaluation. For the domain of pain/discomfort, the question consists of 1 item and is not designed for any specific symptom. Therefore, it is possible that the patient's evaluation did not change significantly because of multiple symptoms coexisting as shown by the assessment of medical staff. For the domain of anxiety/depression, there were more replies of "no problem" at the first assessment than for other

domains. The patients may have been comparatively stable mentally while being aware of the decline of their physical function.

Evaluations by the medical staff indicated that the patients' pain, appetite loss, and constipation improved significantly during the 2-week period. In addition, on the whole, the number of moderate-to-extreme symptoms decreased significantly. However, dry mouth was not sufficiently palliated and other symptoms, such as fatigue remained stable at the second evaluation. The palliation of these symptoms may be difficult because of the progression of underlying disease in various care settings.¹⁵⁻¹⁷ In fact, for symptoms other than pain, the barriers to effective symptom management in terminal cancer patients remain unclear.¹⁸