

Fig. 1. Changes in pain intensity between patients surviving 28 days or longer vs. less than 28 days.

This study failed to demonstrate beneficial effects on communication levels and cognitive dysfunction such as delirium, despite an increased performance status and reduced opioid consumption. The possible interpretations are (1) lack of sensitivity of outcome measures, especially the retrospective nature of symptom assessment, (2) cognitive impairment occurring due to not only opioids but also deteriorated general conditions such as hypercalcemia and brain metastasis at an advanced stage, and (3) the small number of subjects resulting in a lack of sample power. In this study, however, six of 19 patients recovered from delirium, suggesting that neural blockade could improve cognitive impairment in some patients, such as those receiving high-dose opioids without other causes influencing cognitive capacity.

The third important finding is the exploration of predictors of successful or unsuccessful interventions. This study identified longer survival as an indicator of success in neural blockade. This result, along with a similar observation,⁶ suggests that earlier referral for neural blockade could contribute to a better quality of life of cancer patients.

This study is preliminary, and has several limitations. First, the retrospective nature of the assessment is an apparent limitation of the evaluation of treatment efficacy. Second, the participating institutions were selected for convenience, and so these findings cannot be automatically generalized to other institutions. Third, long-term efficacy was beyond our study aims. Fourth, no patients in this study received intrathecal opioid therapy, because this

technique was not a common practice in Japan during this study period.

In conclusion, neural blockade was performed in 3.8% of cancer patients who received specialized palliative care in Japan. This could contribute to the improvement of pain intensity, performance status, and opioid consumption without unpredictable serious side effects. A prospective audit study is expected to identify the treatment efficacy of each interventional procedure in palliative care settings.

References

- Ventafriidda V, Tamburini M, Caraceni A, de Conno F, Naldi F. A validation study of the WHO method for cancer pain relief. *Cancer* 1987;59: 850-856.
- Hagan Q, Haddox JD, Abram S, et al. Epidural opiates and local anaesthetic for the management of cancer pain. *Pain* 1991;46:271-279.
- Zech DFJ, Grond S, Lynch J, Hertel D, Lehman KA. Validation of World Health Organisation guidelines for cancer pain relief: a 10-year prospective study. *Pain* 1995;63:65-76.
- Grond S, Zech D, Schug SA, Lynch J, Lehmann KA. Validation of World Health Organization guidelines for cancer pain relief during the last days and hours of life. *J Pain Symptom Manage* 1991;6:411-422.
- Eisenberg E, Carr DB, Chalmers TC. Neurolytic celiac plexus block for treatment of cancer pain: a meta-analysis. *Anesth Analg* 1995;80:290-295.
- de Oliveira R, dos Reis MP, Prado WA. The effects of early or late neurolytic sympathetic plexus block on the management of abdominal or pelvic cancer pain. *Pain* 2004;110:400-408.
- Wong GY, Schroeder DR, Carns PE, et al. Effect of neurolytic celiac plexus block on pain relief, quality of life, and survival in patients with unresectable. Pancreatic cancer. *JAMA* 2004;291:1092-1099.
- Mercadante S. Celiac plexus block versus analgesics in pancreatic cancer pain. *Pain* 1993;52: 187-192.
- Kawamata M, Ishitani K, Ishikawa K, et al. Comparison between celiac plexus block and morphine treatment on quality of life in patients with pancreatic cancer pain. *Pain* 1996;64:597-602.
- Mercadante S, Catala E, Arcuri E, Casuccio A. Celiac plexus block for pancreatic cancer pain: factors influencing pain. Symptoms and quality of life. *J Pain Symptom Manage* 2003;26:1140-1147.
- Slatkin NE, Rhiner M. Phenol saddle blocks for intractable pain at end of life: report of four cases

and literature review. *Am J Hosp Palliat Care* 2003;20:62-66.

12. Hassenbusch SJ, Portenoy RK, Cousins M, et al. Polyanalgesic consensus conference 2003: an update on the management of pain by intraspinal drug delivery-report of an expert panel. *J Pain Symptom Manage* 2004;27:540-563.

13. Baker L, Lee M, Regnard C, Crack L, Callin S. Evolving spinal analgesia practice in palliative care. *Palliat Med* 2004;18:507-515.

14. Smith TJ, Staats PS, Deer T, et al. Randomized clinical trial of an implantable drug delivery system compared with comprehensive medical management for refractory cancer pain: impact on pain, drug-related toxicity, and survival. *J Clin Oncol* 2002;20:4040-4049.

15. Smith TJ, Coyne P. Implantable drug delivery systems (IDS) after failure of comprehensive medical management (CMM) can palliate symptoms in the most refractory cancer pain patients. *J Palliat Med* 2005;8:736-742.

16. Miyashita M, Matoba K, Sasahara T, et al. Reliability and validity of the Japanese version of the Support Team Assessment Schedule (STAS-J). *Palliat Support Care* 2004;2:379-385.

17. Morita T, Tsuchida J, Inoue S, Chihara S, Oka K. Communication Capacity Scale and Agitation Distress Scale to measure the severity of delirium in terminally ill cancer patients: a validation study. *Palliat Med* 2001;15:197-206.

18. Morita T, Tei Y, Inoue S. Agitated terminal delirium and association with partial opioid substitution and hydration. *J Palliat Med* 2003;6:557-563.

19. Morita T, Hyodo I, Yoshimi T, et al. Association between hydration volume and symptoms in terminally ill cancer patients with abdominal malignancies. *Ann Oncol* 2005;16:640-647.

20. Hanks GCW, Cherny N. Opioid analgesic therapy. In: Doyle D, Hanks GCW, MacDonald N, eds. *Oxford textbook of palliative medicine*, 2nd edn. New York: Oxford Medical Publications, 1998: 331-355.

Appendix

Communication Capacity Scale (Item 4)

0 Patients can voluntarily express themselves clearly, even when the theme is complex.

1 Patients are able to voluntarily express themselves clearly, but the contents are limited to simple matters. For example, they only use short sentences consisting of two or three words such as "It hurts" or "I want some water."

2 Patients can express themselves voluntarily, but the contents are slightly incoherent. Or,

although patients do not express themselves voluntarily, they are verbally able to respond meaningfully when stimulated.

3 Patients can voluntarily express themselves, but the contents are obviously incoherent. Or, patients do not express themselves and cannot verbally respond meaningfully even when stimulated.

A pilot study of transformation, attributed meanings to the illness, and spiritual well-being for terminally ill cancer patients

MICHIYO ANDO, PH.D., R.N.,¹ TATSUYA MORITA, M.D.,² VIRGINIA LEE, PH.D.,³ AND TAKUYA OKAMOTO, M.D.⁴

¹Faculty of Nursing, St. Mary's College, Kurume City, Fukuoka, Japan

²Department of Palliative and Supportive Care, Palliative Care Team and Seirei Hospice, Seirei Mikatahara General Hospital, Hamamatsu-shi Shizuoka, Japan

³Department of Nursing Research, McGill University Health Centre, Montreal, Canada

⁴Palliative Care Unit, Toyo Onsen Hospital, Tokyo, Japan

(RECEIVED February 2, 2008; ACCEPTED February 16, 2008)

ABSTRACT

Objective: The present study investigated what types of transformation terminally ill cancer patients experienced from diagnosis until the terminal stage, what meanings terminally ill cancer patients attributed to their illness, and whether or not those who attributed positive meaning to their illness achieved high levels of spiritual well-being as a preliminary study.

Method: Ten terminally ill cancer patients in the hospice wards of two general hospitals participated. A clinical psychologist conducted a semistructured interview with the patients individually for about 60 min. Patients completed the FACIT-Sp and HADS before the interview and talked about the meanings of cancer experience. The contents of the interviews were analyzed qualitatively. Patients were separated into high and low levels of spiritual-well being by the median of FACIT-Sp scores.

Results: Three types of transformation were extracted: "group with peaceful mind," "group with both positive attitude and uneasy feeling," and "groups with uneasy feeling." As attributed meanings to the illness, five categories were extracted: "positive meaning," "natural acceptance," "negative acceptance," "search for meaning," and "regret and sorrow." Patients in the high level spiritual well-being group attributed the meaning of illness to "positive meaning" and "natural acceptance," and those in the low level spiritual well-being group attributed it to "regret and sorrow" and "search for meaning."

Significance of results: Some Japanese terminally ill cancer patients experienced positive transformation, and patients who attributed "positive meaning" and "natural acceptance" to their illness experience achieved high levels of spiritual well-being.

KEYWORDS: Attributed meaning, Spiritual well-being, Terminally ill cancer patients

INTRODUCTION

Spiritual well-being is one of the most important factors in any human's quality of life. The fact that a correlation between low spiritual well-being and the desire for death and thoughts about suicide is more than that in depression (McClain et al., 2003) shows

the importance of spiritual well-being. It allows a person to experience transcendent meaning in life (Puchalski & Romer, 2000) and involves concepts of "faith" and "meaning" (Karasu, 1999). For terminally ill cancer patients, the meaning of their lives or meaning of their illness experience is important.

Attributed meaning to the illness experience is an affective factor in psychosocial adjustment for cancer patients. Stanton et al. (2002) found that patients with breast cancer who found positive meaning in their illness were psychologically adaptive. Tomich

Address correspondence and reprint requests to: Michiyo Ando, St. Mary's College, Tsubukuhonmachi 422, Kurume city, Fukuoka, Japan. E-mail: andou@st-mary.ac.jp

and Helgeson (2002) demonstrated that the ability to successfully reconstitute a meaning of life following diagnosis of cancer has been associated with general measures of psychological adjustment. These studies are based on the meaning-making coping theories such as the "Theory of Cognitive Adaptation" (Taylor, 1983) or the "Transactional Model of Stress and Coping" (Park & Folkman, 1997), in which, when people find meanings in a stressful life event and recognize it as important, they can cope with it. Taylor (2000) showed that breast cancer survivors became adaptive psychologically when they found positive meanings in their illness experience. Though patients were shocked at the diagnosis, they found positive meanings and experienced psychological positive transformation. This transformation processes included four phases; encountering darkness, converting darkness, encountering light, reflecting light.

Though Taylor (2000) investigated the positive transformation type of cancer survivors whose psychological status changed from negative to positive and the kinds of meanings for them, it was not clear what other transformation types there were, what kinds of meanings terminally ill cancer patients attributed to the cancer experience, and patients who attributed positive meanings were adaptive in spiritual well-being. Because there were some differences in views for good death between Western culture and Japan (Hirai et al., 2006), for example, autonomy in decision making, we expected that there were other kinds of transformation types or meanings for Japanese patients. The present study investigated (1) what types of transformation terminally ill cancer patients experienced, (2) what kind of meanings terminally ill cancer patients attributed to the illness experience, and (3) patients who attributed positive meaning to the illness achieved the high spiritual well-being.

METHOD

Sample

The participants were cancer patients from the palliative care unit of two general hospitals (Table 1). The inclusion criteria for this study were patients with advanced-stage cancer III/IV, without cognitive impairment, and 20 years of age or older. During the 3-month study period, 10 patients were recruited. To assess their performance status, we used the Eastern Cooperative Oncology Group performance status scale Oken et al. (1982).

Measures

To measure the state of spiritual well-being and subjects' psychological state, we used the Japanese

version of the Functional Assessment of Chronic Illness Therapy—Spiritual Well-Being Scale (FACIT-Sp; Peterman et al., 2002). The validity and reliability of the Japanese version of the FACIT-Sp is well established (Noguchi et al., 2004). The range of the α reliability score was from .81 to .91. The standard mean score for the normal population is 32. High scores mean high levels of spiritual well-being. Anxiety and depression were also measured using the Japanese version of the Hospital Anxiety and Depression Scale (HADS; Kitamura, 1993; Zigmond & Snaith, 1983). High scores mean high anxiety and depression. The cut-off point of the HADS is 10/11 and patients scoring over 11 may have some problems.

Procedure

The interviewer was a clinical psychologist, and all interviews were conducted individually. St. Mary's College ethical board permitted this study. The interviews were based on the questions reported in Taylor's (2000) study with breast cancer patients and typically lasted half an hour. Each semistructured interview involved two questions: "Please recall how your mood or psychological status has changed from the diagnosis until now." and "What does having cancer mean to you?" It was an open-ended question, and the patients were permitted to talk freely. The interviews were written down. We did not record the interviews because most of the patients did not want to be recorded. The interview session was only one time because patients at this period in these hospices were in very advanced stages and we estimated that it would be impossible to meet all participants two times. We met 10 patients because we wanted to know the tendency as a very preliminary study.

Data Analysis

As a quantitative analysis to find transformation types and kinds of meanings, for initial coding, the transcribed interviews of each subject were analyzed line by line, and any contents that were considered to be related to meanings were extracted. The extracted codes were classified, codes with a common meaning were categorized together, and categories and subcategories were formed and integrated. Joint analytical meetings of investigators were held on some occasions for this purpose. Strategies for increasing the trustworthiness of the data and analysis included having the investigator conduct all interviews and analysis, concurrent data collection, and analysis until data were saturated. Two researchers coded and categorized. The investigator also obtained feedback and validation about the methods and preliminary analysis from a nurse researcher expert in

Table 1. Patients' background

Patient	Age	Gender	Tumor site	Stage	Performance status
Patient 1	54	Female	Nerve fiber	IV	4
Patient 2	59	Male	Oral	IV	2
Patient 3	61	Male	Lung	IV	4
Patient 4	83	Female	Lung	III	3
Patient 5	51	Female	Liver	IV	4
Patient 6	62	Male	Stomach	IV	4
Patient 7	76	Female	Rectum	IV	4
Patient 8	42	Male	Lung	IV	4
Patient 9	76	Female	Rectum	IV	3
Patient 10	66	Female	Liver	IV	4

qualitative approaches. The FACIT-Sp and HADS scores were used to examine what kinds of meanings terminally ill cancer patients attributed to the illness. Patients were separated into two groups by the median of the FACIT-Sp scores.

RESULTS

Types of Transformation

We extracted three types of transformation. One is the "group with a peaceful mind." Patient 4 felt dislike of cancer when she was diagnosed; however, she changed her mind such that she followed her sons' advice and preferred to let matters take their course. Patient 7 was an elderly woman and she remembered her young, good days and was satisfied with them. Patient 9 lost her will to live when she was diagnosed; however, she encountered art or other patients' efforts, found meanings to live, and changed positively. These patients' mood was peaceful.

The second was the "group with positive attitude and uneasy feelings." Patient 5 was much surprised when she was diagnosed, and recognized others' kindness slowly. However, she suffered from the discrepancy between her self-image and the present status. Patient 1 had not considered her illness serious at first; however, her physical strength suddenly decreased. She almost accepted her present status, but she was very sorry simultaneously. These patients felt both good and bad mood psychologically.

The third group was the "group with uneasy feelings." Patients in this group had expectation for cure of their cancer; however, their physical conditions were serious and they felt anxiety, regret, sorrow, worry, or pain.

Meanings of Cancer

The answers obtained to the question, "What does having cancer mean to you?" were then grouped into five categories.

Positive Meaning

Patient 9 lost her will to live when she was diagnosed. However, she had been touched by the beauty of music and art, and had encountered other patients who made an effort to live. She found positive meaning such as "I learned many things here. Transcendent powers may guide me here" (*recognition of transcendence*). Patient 5, Patient 6, and Patient 9 recognized kindness of others after becoming ill and became compassionate towards them (*profound appreciation toward others*) and had wished to do something to return the kindness to other people (*wish to do based on illness*). Patient 2 suffered from side effects as a result of long-term medical treatment, but he praised himself for coping with medical treatments (*increased self-respect*). Some patients reflected upon their unconcern about their condition and appreciated their health (*healthy perspective about self*).

Natural Acceptance

Patient 4 and Patient 7 said, "I do not dwell on matters seriously." Patient 7 was an old woman and satisfied with her life. She said, "I let things take their course." She thought that her illness was one of many life events and accepted it naturally. Patient 4 had a lot of family support and had no worries such as economy or family problems. These patients stopped controlling everything and left matters to take their own course.

Negative Acceptance

Patient 1 said, "There is no way for me to control the disease." She could not move any more and felt helpless; thus she made an effort to let go of her control over almost all things. Patient 8 wanted to do many things such as travel and volunteer work; however, he had to give up his dreams. Thus he accepted the present states negatively. And, Patient 10 said sadly that "I tried to take much complementary medicine;

however, I could not do anything effectively. Now, I think that I should let the matter take its course."

Search for Meaning

Patient 2, Patient 3, Patient 5, and Patient 8 asked why they had gotten cancer. Some of them reasoned that the illness was caused by "blasphemy" or "karma."

Regret and Sorrow

Some patients felt that their way of living had changed unexpectedly and unintentionally. They either wanted to do something or had many things left to do. They experienced profound regret. Some patients experienced sorrow for other reasons. One patient said, "I am very sorry that I cannot play my role."

Relationship between Spiritual Well-being and Positive Meaning

Table 2 shows both the FACIT-Sp scores and attributed meanings to illness in addition to HADS. We can classify patients into two groups based on the mean FACIT-Sp score (32) for the normal population. Patients over the mean score constituted the high spiritual well-being group and those below the mean score constituted the low spiritual well-being group. Observing main attributed meanings to the illness, patients in the high spiritual well-being group attributed positive meanings or a natural acceptance to the illness. On the other hand, those in the low spiritual well-being group attributed "regret and sorrow," and "search for meaning" to the illness.

DISCUSSION

Types of Transformation

Three types of transformation of "group with a peaceful mind," "group with positive attitude and uneasy feelings," and "group with uneasy feelings," were extracted. The type "group with peaceful mind" is similar to "positive transformation" in Taylor (2000) in the point that patients were adaptive. And these three types of transformation accord with a study for cancer survivors (Carpenter et al., 1999). They also extracted three types of transformation: positive transformation; minimal transformation, in which patients felt some self-transformation; and feeling stuck, in which patients wanted to change, but they could not. These results suggest that there are similarities in transformation types both in cancer survivors and terminally ill cancer patients.

Moreover, as for trigger of positive transformation, Patient 9 conspicuously changed from a negative psychological status to a positive one by encountering good art and other patients' effort. As Compton (2005) demonstrated that aesthetic sense is important for increasing humans' well-being, good music promoted the positive transformation. Although Coward (2003) demonstrated an intervention to facilitate self-transcendence, we need to clarify factors of triggers of transformation much more in order to develop suitable interventions to support patients in the "group with uneasy feelings."

Meaning of Cancer

There were five kinds of attributed meanings (positive meaning, natural acceptance, negative acceptance,

Table 2. Attributed meaning of high and low spiritual well-being groups separated by the standardized means of FACIT-Sp score (32)

Patient	FACIT-Sp	HADS	Attributed meanings to the illness	
			Main meaning	Submeaning
High score group				
Patient 9	48	3	Positive meanings	
Patient 4	47	4	Natural acceptance	
Patient 5	37	17	Positive meaning	Search for meaning
Patient 7	33	14	Positive meaning	Natural acceptance
Low score group				
Patient 1	24	15	Regret and sorrow	Negative acceptance
Patient 3	23	19	Search for meaning	
Patient 8	21	12	Search for meaning	Negative acceptance
Patient 10	21	14	Regret and sorrow	Negative acceptance
Patient 6	19	18	Regret and sorrow	Positive meaning
Patient 2	16	9	Regret and sorrow	Positive meaning

search for meaning, and regret and sorrow). Moreover, in the positive meaning, there were subcategories (recognition of transcendence, appreciation toward others, increased self-respect, healthy perspective about self, wish to do based on illness).

About positive meaning, "recognition of transcendence" in the present study accorded with "intensified spiritual awareness" in Taylor (2000), though there is a difference between Japanese and Americans; American participants referred to God as spiritual awareness in Taylor, whereas Japanese patients referred to transcendent power such as immense respect for nature more than a specific God (Ama, 2006). Recognition of transcendence of Patient 9 is similar to results of a previous study that as many as 50% of cancer patients report becoming "more religious" or that "illness has strengthened their faith (Brady et al., 1999)." Because the number of participants was too small, we need to increase the number of participants and examine how many patients experience recognition of transcendence or religious matters and how its recognition functions in psychological adjustment.

"Natural acceptance" may be related to the Japanese Zen way of thinking (Yanagida, 2005). People know that death strikes suddenly and mercilessly; thus, they live life to the fullest every day. They wish to lead a good life and welcome a peaceful death. According to Kohli and Dalal (1998), cancer patients in Allahabad, India, or Hindu women attributed their illness to metaphysical beliefs—fate, God's will, karma. Belief that God's will had caused their cancer was associated with a lack of perceived controllability over their illness; however, it was also associated with stronger feelings of recovery for cancer. Although an attribution of beyond my control may be considered undesirable in cultures where people are encouraged to take control over their illness, in other cultures the same attribution may be seen in a more positive light (MacLachlan, 2006). In Japanese culture, natural acceptance as a way of thinking in which patients let matters take their course naturally may be psychologically adaptive.

Moreover, we may be able to add a concept of "natural acceptance" to previous studies' categories (global meaning, appraised meaning, search for meaning, and meaning as outcome) by Park and Folkman (1997) and Lee et al. (2004).

Relationships between Positive Meaning and Spiritual Well-being

Patients who found "positive meaning" achieved high spiritual well-being. In addition to the previous studies that showed that meaning related to the distress level of cancer survivors (Jim & Anderson, 2007), we suggest that positive attributed meaning

to the illness relates to the high levels of spiritual well-being of terminally ill cancer patients. Though Park (2007) explained the pathway between spirituality and health (physical function and well-being) in the meaning schema, we will show a pathway between kinds of attributed meaning to the illness and the spiritual well-being of terminally ill cancer patients empirically.

Moreover, patients who found "natural acceptance" also achieved high spiritual well-being. This attitude may relate to a concept of "mindfulness." Mindfulness is the awareness that emerges through paying attention on purpose, in the present moment, without judgment of things as they are (Williams et al., 2007). Because there are few studies about this therapy for terminally ill cancer patients or Japanese patients, we will examine characteristics of relationships between mindfulness psychotherapy and natural acceptance.

Clinical Implication and Limitation

There are some interventions on spiritual well-being such as listening to patients' personal stories (O'Connor & Wicker, 1995), meaning-centered group psychotherapy (Breitbart, 2002), meaning-making interventions (Lee et al, 2006), and the short-term life review (Ando et al., 2008). However, there are few interventions tailored to kinds of attributed meanings to the illness. Following a suggestion by Tang et al. (2007) that meaning-searching process brings growth and transformation through the cancer experience, we need to examine relationships between meaning-making processes and spiritual well-being, clarifying the differences among cultures.

Lastly, as the number of participants was too small, we can not generalize results of the present study. A study to increase more participants will be promising.

REFERENCES

- Ama, T. (2006). *Why Japanese do not have religion*. Tokyo: Chikuma Shinsyo (in Japanese).
- Ando, M., Morita, T., Okamoto, T., et al. (2008). One-Week Short Term Life Review can improve spiritual well-being of terminally ill cancer patients. *Psycho-Oncology*, 17, 885–890.
- Brady, M.J., Peterman, A.H., Fitchett, G., et al. (1999). A case for including spirituality in quality of life measurement in oncology. *Psycho-Oncology*, 8, 417–428.
- Breitbart, W. (2002). Spirituality and meaning in supportive care: Spirituality- and meaning-centered group psychotherapy interventions in advanced cancer. *Supportive Care in Cancer*, 10, 272–280.
- Carpenter, J.S., Brockopp, D.Y. & Andykowski, M.A. (1999). Self-transcendence as a factor in the self-esteem and well-being of breast cancer survivors. *Journal of Advanced Nursing*, 29, 40–41.

- Compton, W.C. (2005). *Introduction to Positive Psychology*. Belmont, CA: Thomson/Wadsworth.
- Coward, D.D. (2003). Facilitation of self-transcendence in a breast cancer support group. *Oncology Nursing Forum*, 10, 291-300.
- Hirai, K., Miyashita, M., Morita, T., et al. (2006). Good death in Japanese cancer care: A qualitative study. *Journal of Pain and Symptom Management*, 31, 140-147.
- Jim, H.S. & Andersen, B.L. (2007). Meaning in life mediates the relationship between social and physical functioning and distress in cancer survivors. *British Journal of Health Psychology*, 12, 363-381.
- Karasu, B.T. (1999). Spiritual psycho-therapy. *American Journal of Psychotherapy*, 53, 143-162.
- Kitamura, T. (1993). Hospital Anxiety and Depression Scale (in Japanese). *Seishinka Shindangaku*, 4, 371-372.
- Kohli, N. & Dalal, A.K. (1998). Culture as a factor in causal understanding of illness: A study of cancer patients. *Psychology and Developing Societies*, 10, 115-129.
- Lee, V., Cohen, S.R., Edgar, L., et al. (2004). Clarifying "meaning" in the context of cancer research: A systematic literature review. *Palliative and Supportive Care*, 2, 291-303.
- Lee, V., Cohen, S.R., Edgar, L., et al. (2006). Meaning-making and psychological adjustment to cancer: Development of an intervention and pilot results. *Oncology Nursing Forum*, 33, 291-302.
- MacLachlan, M. (2006). *Culture and Health: A Critical Perspective towards Global Health*. Chichester, UK: John Wiley & Sons.
- McClain, C.S., Rosenfeld, B., & Breitbart, W. (2003). Effects of spiritual well-being on end-of-life despair in terminally ill cancer patients. *Lancet*, 361, 1603-1607.
- Noguchi, W., Ono, T., Morita, T., et al. (2004). An investigation of reliability and validity to Japanese version of Functional Assessment of Chronic Illness Therapy-Spiritual (FACIT-sp). *Japan Journal of General Hospital Psychiatry*, 16, 42-47.
- O'Connor, A.P. & Wicker, C.A. (1995). Clinical commentary: Promoting meaning in the lives of cancer survivors. *Seminars in Oncology Nursing*, 11, 68-72.
- Oken, M.M., Creech, R.H., Tormey, D.C., et al. (1982). Toxicity and response criteria of the Eastern Cooperative Oncology Group. *American Journal of Clinical Oncology*, 5, 649-655.
- Park, C.L. (2007). Religiousness/spirituality and health: A meaning systems perspective. *Journal of Behavior Medicine*, 30, 319-328.
- Park, C.L. & Folkman, S. (1997). Meaning in the context of stress and coping. *Review of General Psychology*, 1, 115-144.
- Peterman, A.H., Fitchett, G., Brady, M.J., et al. (2002). Measuring Functional Assessment of Chronic Illness Therapy-Spiritual Well-Being Scale (FACIT-Sp). *Annals of Behavioral Medicine*, 24, 49-58.
- Puchalski, C. & Romer, A.L. (2000). Taking a spiritual history allows clinicians to understand patients more fully. *Journal of Palliative Medicine*, 3, 129-137.
- Stanton, A.L., Danoff-Burg, S. & Huggins, M.E. (2002). The first year after breast cancer diagnosis: Hope and coping strategies as predictors of adjustment. *Psycho-Oncology*, 11, 93-102.
- Tang, V.Y., Lee, A.M., Chan, C.L., et al. (2007). Disorientation and reconstruction: The meaning searching pathways of patients with colorectal cancer. *Journal of Psychosocial Oncology*, 25, 77-102.
- Taylor, S.E. (1983). Adjustment to threatening events: A theory of cognitive adaptation. *American Psychologist*, 38, 1161-1173.
- Taylor, E.J. (2000). Transformation of tragedy among women surviving breast cancer. *Oncology Nursing Forum*, 27, 781-788.
- Tomich, P.L. & Helgeson, V.S. (2002). Five years later: A cross-sectional comparison of breast cancer survivors with healthy women. *Psycho-Oncology*, 11, 154-169.
- Williams, M., Teasdale, J., Segal, Z., et al. (2007). *The mindful way through depression: Freeing yourself from chronic unhappiness*. New York: Guilford Press.
- Yanagida, S. (2005). *Zen and Japanese Culture*. Tokyo: Kodansya (in Japanese).
- Zigmond, A.S. & Snaith, R.P. (1983). The Hospital Anxiety and Depression Scale. *Acta Psychiatrica Scandinavica*, 67, 361-370.

breathing, respiratory rate, and oxygen saturation in dyspnea. *J Pain Symptom Manage* 2002;23(2):157-160.

12. Benitez-Rosario MA, Martin AS, Feria M. Oral transmucosal fentanyl citrate in the management of dyspnea crises in cancer patients. *J Pain Symptom Manage* 2005;30(5):395-397.

13. Christrup LL, Foster D, Popper LD, Troen T, Upton R. Pharmacokinetics, efficacy, and tolerability of fentanyl following intranasal versus intravenous administration in adults undergoing third-molar extraction: a randomized, double-blind, double-dummy, two-way, crossover study. *Clin Ther* 2008;30(3):469-481.

Palliative Care in Japan: Shifting from the Stage of Disease to the Intensity of Suffering

To the Editor:

The health care system for specialized palliative care services in Japan is shifting from "end-of-life care" to "palliation of suffering," in accordance with the World Health Organization recommendation that palliative care should be provided for all cancer patients regardless of disease stage.¹

Since 1990, the Japan Ministry of Health, Labour and Welfare has actively facilitated palliative care by designating palliative care units as eligible for national health insurance coverage. The increase in the number of palliative care units has been dramatic, from five to over 177 in 2008, but still, only 6% of all cancer deaths occur in units.² The patients who have been approved for admission to palliative care units have been defined as cancer patients in the "terminal stage" and the mean length of stay on a palliative care unit has been 43 days. A nationwide survey showed that about half of the patients and families reported that the timing of the referral was "too late," and 85% of families reported that patients had had distressing physical symptoms before admission to the palliative care unit.³

These findings gave impetus to the passage of the Cancer Control Act in April 2007. The aims of this law are to promote cancer prevention and early detection, to disseminate quality palliative care, and to promote cancer

research. The Ministry of Health, Labour and Welfare is focusing on palliative care, and has launched multiple nationwide projects to facilitate the dissemination of palliative care.⁴ In 2007, one of these actions was to change the criteria of palliative care admission to include all "cancer patients with a considerable level of suffering." Admission should not be based on the stage of disease. The Ministry of Health, Labour, and Welfare also obliged all 353 regional cancer centers throughout Japan to establish palliative care teams, and approved palliative care teams as eligible for national health insurance coverage.

We welcome these changing policies of the Japanese government, and believe that increasing numbers of patients will receive appropriate specialized palliative care as a result. The expected outcomes include an increase in the number of the patients receiving specialized palliative care, improvement of patient symptom experience among general hospitals and outpatient clinics, and an increase in the availability of palliative care units for patients who are not close to death but are experiencing complex symptomatology. We are monitoring the effects through nationwide surveys and administrative data, and will report the main impact within several years.

Tatsuya Morita, MD
Department of Palliative and Supportive Care, Palliative Care Team, and Seirei Hospice
Seirei Mikatahara General Hospital
Shizuoka, Japan

Mitsunori Miyashita, RN, PhD
Department of Adult Nursing/
Palliative Care Nursing
School of Health Sciences
and Nursing
Graduate School of Medicine
The University of Tokyo
Tokyo, Japan

Satoru Tsuneto, MD, PhD
Department of Palliative Medicine
Osaka University Graduate School of Medicine
Osaka, Japan

Yasuo Shima, MD
Department of Palliative Medicine
Tsukuba Medical Center Hospital
Ibaraki, Japan

doi:10.1016/j.jpainsymman.2008.06.004

References

1. World Health Organization. National cancer control programmes. Policies and managerial guidelines, 2nd ed. Geneva: WHO, 2002.
2. Japan Hospice Palliative Care Foundation and Hospice Kanwakea Hakusho. White Paper on Hospice Palliative Care in 2008. [in Japanese]. Seikaisha.
3. Morita T, Akechi T, Ikenaga M, et al. Late referrals to specialized palliative care service in Japan. *J Clin Oncol* 2005;23:2637-2644.
4. Yamagishi A, Morita T, Miyashita M, et al. Palliative care in Japan: current status and a national-wide challenge to improve palliative care by the Cancer Control Act and the Outreach Palliative Care Trial of Integrated Regional Model (OPTIM) study. *Am J Hosp Palliat Care* 2008 Jul 3; [Epub ahead of print].

Palliative Care in Japan: Current Status and a Nationwide Challenge to Improve Palliative Care by the Cancer Control Act and the Outreach Palliative Care Trial of Integrated Regional Model (OPTIM) Study

Akemi Yamagishi, RN, MN, Tatsuya Morita, MD, Mitsunori Miyashita, RN, PhD, Nobuya Akizuki, MD, PhD, Yoshiyuki Kizawa, MD, Yutaka Shirahige, MD, PhD, Miki Akiyama, PhD, Kei Hirai, PhD, Tadashi Kudo, MA, Takuhiro Yamaguchi, PhD, Asuka Fukushima, RN, and Kenji Eguchi, MD, PhD

Palliative care is an essential part of integrated cancer treatment. To improve palliative care throughout Japan, a nationwide demonstration project, the Outreach Palliative Care Trial of Integrated Regional Model (OPTIM) study, is ongoing. This article reviews the current status and the problems of palliative care in Japan and introduces the OPTIM study. Although the number of palliative care services is increasing, empirical evidence shows the quality of life of cancer patients is still inadequate. The OPTIM study is an intervention trial targeting 4 areas across Japan. Primary end points are

quality of care reported by patients as well as the bereaved family, number of patients who received specialized palliative care services, and place of death. The interventions are comprehensively designed to cover all areas identified by the national task force. The OPTIM study will contribute to improve patients' quality of life by proposing a regional palliative care model suitable for Japan.

Keywords: palliative care; regional trial; neoplasms

Palliative care is an essential part of integrated cancer treatment.¹ Although palliative care should be provided throughout a whole region, a regionalized palliative care model has not been established in Japan. The Outreach Palliative Care Trial of Integrated Regional Model (OPTIM) study was therefore launched in 2007 to demonstrate a model suitable for the dissemination of high-quality palliative care in the Japanese community.

The two primary aims of this action paper are to review the current status and the problems of palliative care in Japan and provide an overview of the OPTIM study.

Current Status of Palliative Care in Japan

Health Care System and Specialty Training in Palliative Care

The health care system for specialized palliative care services in Japan has been progressing rapidly in this decade. Japan has 3 types of specialized palliative care services: palliative care units, hospital palliative care teams, and specialized home-care clinics.

Palliative care units are called "palliative care units" or "hospices" depending on their religious

background, but their clinical roles are essentially the same: intensive symptom control, psychosocial support, and end-of-life care for incurable cancer patients and their families. The first palliative care unit was established in 1981 in a private Christian hospital (Seirei Hospice).

The next landmark in the national strategy of palliative care was in 1989, with the publication of the end-of-life care report by the Ministry of Health, Labour and Welfare. This report resulted in the first government-approved palliative care units eligible for national health insurance coverage in 1990. The number of palliative care units has since dramatically increased, from 5 in 1990 to more than 170 in 2006.^{2,3} Most palliative care units belong to general hospitals and provide integrated palliative care by an interdisciplinary team. This is the most common type of specialized palliative care service in Japan.

Hospital palliative care teams were first covered by national medical insurance in 2002.⁴ The expected role of palliative care teams is to provide specialized palliative care to all cancer patients, including those receiving active cancer treatment, not only those in the advanced stage. For a palliative care team to be approved for national health insurance coverage, it must fulfill the requirements of the Ministry of Health, Labour and Welfare: interdisciplinary team activity, including at least 1 attending palliative care physician, a psychiatrist, and certified advanced-practice nurse. In 2007 the number of certified palliative care teams was approximately 60, and many hospitals intend to establish palliative care team activity.

Specialized home-care support clinics were first defined in 2006. These clinics are expected to provide home care for a wide range of patients in the community by a multidisciplinary team with 24-hour service, although the specialty requirement is still poorly defined. The clinics can obtain additional remuneration for their practices for terminally ill patients at home, and 8600 clinics have been established.

As for specialty training in palliative care, the Japanese Society for Palliative Medicine was established in 1996 as an academic association to conduct research, education, and dissemination of palliative care. It had approximately 6000 members in 2006. The number of advanced practice nurses is furthermore rapidly increasing: 79 oncology-certified nurse specialists and 891 certified nurses, including 420 in palliative care, 267 in pain management, and 204 in chemotherapy.

Evidence to Suggest Poor Quality of Life of Cancer Patients

To date, no nationwide representative survey has clarified how cancer patients and their family members evaluated the quality of palliative care they actually received, although multiple surveys to understand the experience of patients and families are now ongoing. Empirical evidence, nonetheless, suggests a poor quality of life for cancer patients in Japan.

First, in a multicenter questionnaire survey of 630 bereaved family members of cancer patients admitted to palliative care units, 85% of 318 responding families reported that their relative had had distressing physical symptoms before admission to the palliative unit, and 50% reported that considerable or much improvement was necessary in the care they had received.⁵

Second, less than 10% of Japanese cancer patients received specialized palliative care services: 6.6% from palliative care teams and 2.2% from palliative care units.^{3,6} Multiple Western studies have suggested that specialized palliative care services contribute to improving patients' quality of life, and family satisfaction was extremely high for inpatient palliative care services in Japan.^{2,7,8} In the United Kingdom and United States, more than half of all cancer patients receive specialized palliative care.^{9,11}

From the Japan Cancer Society (AY, AF) and Japan Department of Adult Nursing/ Palliative Care Nursing, Graduate School of Medicine, The University of Tokyo, Tokyo (AY, MM); Department of Palliative and Supportive Care, Palliative Care Team, and Seirei Hospice, Seirei Mikatahara General Hospital, Shizuoka (TM); Psycho-Oncology Division, Research Center for Innovative Oncology, National Cancer Center Hospital East, Chiba (NA); Graduate School of Comprehensive Human Science, University of Tsukuba, Ibaraki (YK); Shirahige Clinic, Nagasaki (YS); Faculty of Policy Management, Keio University, Kanagawa (MA); Graduate School of Human Sciences (TK, KH), and Center for the Study of Communication-Design, Department of Complementary and Alternative Medicine, Graduate School of Medicine, The University of Osaka, Osaka (KH); Department of Clinical Trial Data Management, Graduate School of Medicine, The University of Tokyo Hospital, Tokyo (TY); and the Division of Medical Oncology, Teikyo University School of Medicine, Tokyo, Japan (AF, KE).

Address correspondence to: Tatsuya Morita, MD, Seirei Mikatahara General Hospital, 3453 Mikatahara-cho, Hamamatsu, Shizuoka 433-8558, Japan; e-mail: tmorita@sis.seirei.or.jp.

Table 1. Palliative care in Japan, the United Kingdom, and United States of America

Variable	Japan	UK	USA
Cancer deaths per year	326 000	138 000	550 000
Use of specialized palliative care services, % of all cancer deaths			
Inpatient service	6.6	26	
Hospital consultation service	2.2	74	
Home-based service		69	99
Place of death, % of all cancer deaths			
Home	5.7	22	39
Palliative care unit or inpatient hospice	5.3	16	
Hospital or nursing home	86	60	54

Abbreviations: UK, United Kingdom; USA, United States of America.

(Table 1). The low involvement of specialized palliative care services suggests a lower quality of life for cancer patients in Japan.

Third, a discrepancy exists between the place where the patient preferred to die and the actual place of death. Although 50% of the Japanese general public expresses a preference to spend their final days at home and 30% in a palliative care unit,¹² the actual rate of death at home and inpatient specialized palliative care service is 5.7% and 5.5%, respectively, and most cancer patients die in hospitals (Table 1).¹³⁻¹⁵ Because the location of death is an important element of the quality of life,¹⁶ this finding suggests a poor quality of life for Japanese cancer patients.

Finally, opioid consumption is one sixtieth of that in the United States and one seventh of that in the United Kingdom.¹⁷ Despite the differences in legal and medical regulations, as well as racial differences, this finding suggests that pain palliation of cancer patients in Japan is still not achieved.

Barriers for Quality Palliative Care

To explore effective strategies to disseminate quality palliative care throughout the country, a national task force was organized and identified the barriers to quality palliative care, which were

1. lack of standardized clinical tools,
2. lack of knowledge about palliative care by the general public,
3. lack of whole-region organization to coordinate community palliative care, and
4. specialized palliative care services less available in community.¹⁸

Lack of Standardized Clinical Tools

Standardized tools are important to maintain the quality and continuity of community palliative care.¹⁹ Despite the variety of frameworks, guidelines, and clinical pathways available in English-speaking countries, in Japan, standard materials have not been developed or are inadequately disseminated. We have completed or are now performing a validation study of several key instruments to modify the original tools suitable for Japanese culture, including the Support Team Assessment Schedule, M.D. Anderson Symptom Inventory, Distress Thermometer, and Liverpool Care Pathway.²⁰⁻²² These instruments are gradually being disseminated to palliative care clinicians, but more distribution efforts to general practice are greatly required.

Lack of Knowledge About Palliative Care

Despite strong empirical evidence that opioids for cancer pain rarely cause addiction, 30% of the Japanese general public believes that they are addictive, and such misapprehension is a significant barrier for better pain management.²³⁻²⁵ Also, 34% of the general public in Japan knows about palliative care units compared with 70% in the United Kingdom.^{12,26} Of note is that although 32% of the Japanese general public believes that palliative care units are a place where patients just wait for death, these negative perceptions significantly decreased after they actually used a specialized palliative care service.^{5,12} This lack of knowledge and misinformation about opioids and palliative care is a considerable barrier to palliative care and pain control at an appropriate time, and education of the general public is of great value.

Lack of Whole-Region Organization to Coordinate Community Palliative Care

The resources potentially available for community cancer patients are becoming more complicated and involve more than a single institution. Although an increasing number of Japanese hospitals have support centers available for community patients, they provide the services principally to their own patients. Whole-region organizations to implement comprehensive coordination for community patients are therefore strongly required.

Specialized Palliative Care Services Less Available

Specialized home-care clinics have just started and are quite primitive in Japan, but specialized palliative care services are currently available only for institutionalized patients. In Europe, community palliative care teams provide consultation services for all patients in the community.²⁷ It is necessary to establish a medical system to provide specialized palliative care that is easily available for community cancer patients.

The OPTIM Study

Overview

From these findings, palliative care in Japan has rapidly progressed in this decade, but many issues still must be resolved. To improve cancer care including palliative care throughout Japan, the Cancer Control Act was established in April 2007. The aims of this law are to promote cancer prevention and early detection, disseminate quality palliative care, and promote cancer research. The Ministry of Health, Labour and Welfare especially focuses on palliative care and has launched multiple nationwide projects to facilitate the dissemination of palliative care. One of these is the OPTIM study, a 5-year project from 2006 to 2011 with a yearly budget of US\$2.5 million.

Aim of the OPTIM Study

The primary aim of the OPTIM study is to evaluate whether a systematic, multi-intervention regional palliative care program can improve the quality of

life of cancer patients in the community. The ultimate purpose of this study is to develop a success model of regional palliative care suitable for Japan.

Subjects and Methods

This is a regional intervention trial measuring the end point before and after intervention. This trial involves 4 intervention regions across Japan with different palliative care system development: Chiba (Kashiwa city, Abiko city, Nagareyama city), Shizuoka (Hamamatsu city), Nagasaki (Nagasaki city), and Yamagata (Tsuruoka, Mikawa-cho; Figure 1). Chiba, Shizuoka, and Nagasaki have a growing organized system to provide palliative care led by a national cancer center, a general hospital, and a regional general practitioner association, respectively. Yamagata has an unorganized system of palliative care.

The study subjects are all residents of the participating regions, including the general public, patients, their families, and health care providers. A total of 0.2 million people are potential participants in this study.

Intervention

The interventions of the OPTIM study are comprehensive and designed to cover all areas identified by the national task force.¹⁸ Each intervention was determined by discussion among clinical specialists and researchers, including palliative care physicians, psychiatrists, nurses, medical social workers, and home care practitioners. In addition, we performed a preliminary survey of 8000 members of the general public and all medical health care providers in the target regions before planning the interventions, and the results were reflected in the details of the interventions.

The interventions include (1) disseminating standardized clinical tools, (2) providing appropriate information about palliative care to the general public, patients and their family, (3) establishing whole-region organization to coordinate community palliative care, and (4) establishing specialized palliative care services available in the community (Table 2).

Clinical tools prepared for this study include (1) assessment tools (comprehensive patient-reported assessment tools consisting of the Japanese version of the M.D. Anderson Symptom Inventory, Distress Thermometer, observer-rating Japanese version of

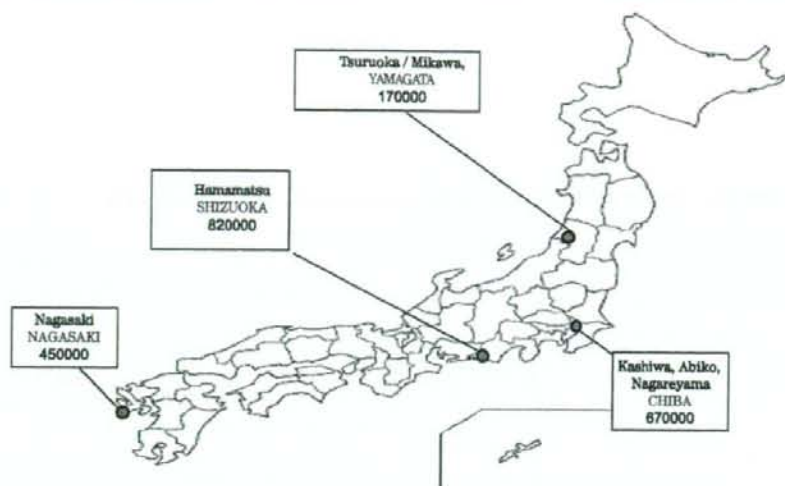


Figure 1. Participating areas of the Outreach Palliative Care Trial of Integrated Regional Model (OPTIM) study are shown with the resident population number.

Table 2. Interventions of the Outreach Palliative Care Trial of Integrated Regional Model Study

Target Area	Intervention	Main Contents
Lack of standardized clinical tools	To standardize and improve the knowledge, skills, and continuity of palliative care in the community	Dissemination of standardized clinical tools via printed and Web materials Interactive workshop and on-demand Web lectures Contents Assessment tools Treatment algorithm Education materials for patients and family members Patient-held records Discharge planning program
Lack of knowledge about palliative care by the general public, patients and their family	To provide appropriate information about palliative care	Distribution of materials via hospitals, Web, visits, patient library, symposia, and local mass-media Materials Leaflets and posters DVDs Books
Lack of whole-region organization to coordinate community palliative care	To establish regional palliative care centers to coordinate community palliative care	Coordination and information service about palliative care services for community residents Regional conference to create local networks and identify local problems
Specialized palliative care services less available in community	To increase availability of specialized palliative care services for community patients	Community palliative care team Educational outreach

Abbreviation: DVD, digital video disc.

the Support Team Assessment Schedule), (2) 3-step ladder-based symptom control algorithm for 9 leading symptoms, (3) educational materials for patients and families, (4) patient-held records, and (5) discharge planning program with a discharge conference as an essential part.

Outcome Measures

Primary end points are quality of palliative care as reported both by patients and the bereaved family, the number of patients who received specialized palliative care services, and place of death. The quality of palliative care is measured by the Care Evaluation Scale, a validated tool to quantify user-perceived quality of care.²⁸

Secondary outcome measures include knowledge, competency, and difficulties of regional physicians and nurses, and quality indicators of regional palliative care, including opioid consumption and the number of nursing agencies providing around-the clock services.

Conclusion

Palliative care in Japan is rapidly progressing through multiple nationwide actions with support from the Cancer Control Act. Palliative care specialists will overcome the challenges and grasp this unique opportunity in cooperation with other specialties to disseminate quality palliative care throughout Japan. The OPTIM study has received much attention and will contribute to improving patient quality of life by proposing a regional palliative care model suitable for Japan. The OPTIM study will be completed in March 2011, and initial results are expected in mid-2012.

References

- World Health Organization. *National Cancer Control Programmes. Policies and Managerial Guidelines*. 2nd ed. Geneva, Switzerland: World Health Organization; 2002.
- Morita T, Chihara S, Kashiwagi T. Family satisfaction with inpatient palliative care in Japan. *Palliat Med*. 2002;16:185-193.
- Japan Hospice Palliative Care Foundation. *Hospice Kamwakea Hakusho* [in Japanese]. 3rd ed. Tokyo, Japan: Seikaisha; 2006.
- Morita T, Fujimoto K, Tei Y. Palliative care team: the first year audit in Japan. *J Pain Symptom Manage*. 2005; 29:458-465.
- Morita T, Akechi T, Ikenaga M, et al. Late referrals to specialized palliative care service in Japan. *J Clin Oncol*. 2005;23:2637-2644.
- Health and Welfare Statistics Association. *Kokumisei-nodoukou 53* [in Japanese]. Tokyo, Japan: Health and Welfare Statistics Association; 2006.
- Higginson IJ, Finlay I, Goodwin DM, et al. Do hospital-based palliative teams improve care for patients or families at the end of life? *J Pain Symptom Manage*. 2002; 23:96-106.
- Higginson IJ, Finlay IG, Goodwin DM, et al. Is there evidence that palliative care teams alter end-of-life experiences of patients and their caregivers? *J Pain Symptom Manage*. 2003;25:150-168.
- The National Council for Palliative Care. *National Survey for Patient Activity Data for Specialist Palliative Care Services MDS Full Report for the Year 2004-2005*. Available from http://www.aswcs.nhs.uk/Informatics/PalliativeCareMinimumDataset/MDS_Full_Report_2005.pdf. Accessed February 10, 2007.
- National Center for Health Statistics. *Health, United States, 2005*. Table 31. Leading causes of death and numbers of deaths, according to sex, race, and Hispanic origin: United States, 1980 and 2003. Available from <http://www.cdc.gov/nchs/data/hs/hs05.pdf>. Accessed February 10, 2007.
- National Hospice and Palliative Care Organization. *NHPCO's Facts and Figures-2005 Findings*. Available from <http://www.alfa.org/files/public/NHPCO2005-facts-and-figures.pdf>. Accessed February 10, 2007.
- 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.
- Ministry of Health, Labour and Welfare. *Population Survey Report 2005*. Available from http://www.dbtk.mhlw.go.jp/toukei/data/010/2005/toukeihyou/0005626/t0124446/MC210000_001.html. Accessed February 10, 2007.
- National Center for Health Statistics. *Worktable 307*. Deaths from 39 selected causes by place of death, status of decedent when death occurred in hospital or medical center, and age: United States, 2003. Available from http://www.cdc.gov/nchs/data/dvs/MortFinal2003_WorkTable307.pdf. Accessed February 10, 2007.
- National Statistics. *Series DH1 no. 37 Mortality Statistics*. Table 17. Deaths: place of occurrence and sex by underlying cause and age-group, 2004. Available from http://www.statistics.gov.uk/downloads/theme_health/Dh1_37_2004/DH1_no_37.pdf. Accessed February 10, 2007.
- Miyashita M, Sanjo M, Morita T, et al. Good death in cancer care: a nationwide quantitative study. *Ann Oncol*. 2007;18:1090-1097.
- The International Narcotics Control Board (INCB). *Tables of Reported Statistics*. Available from http://www.incb.org/pdf/e/tr/nar/2004/narcotics_part4_tables.pdf. Accessed February 10, 2007.

18. Miyashita M, Sanjo M, Morita, et al. Barriers to providing palliative care and priorities for future actions to advance palliative care in Japan: a nationwide expert opinion survey. *J Palliat Med.* 2007;10:390-399.
19. Bruera E, Neumann CM, Gagnon B, et al. Edmonton regional palliative care program: impact on patterns of terminal cancer care. *CMAJ.* 1999;161:290-293.
20. Miyashita M, Matoba K, Sasahara T, et al. Reliability and validity of the Japanese version of the Support Team Assessment Schedule (STAS-J). *Palliat Support Care.* 2004;2:379-385.
21. Okuyama T, Wang XS, Akechi T, et al. Japanese version of the MD Anderson Symptom Inventory: a validation study. *J Pain Symptom Manage.* 2003;26:1093-1104.
22. Shimizu K, Akechi T, Okamura M, et al. Usefulness of the nurse-assisted screening and psychiatric referral program. *Cancer.* 2005;103:1949-1956.
23. Morita T, Miyashita M, Shibagaki M, et al. Knowledge and beliefs about end-of-life care and the effects of specialized palliative care: a population-based survey in Japan. *J Pain Symptom Manage.* 2006;31:306-316.
24. Hojsted J, Sjogren P. Addiction to opioids in chronic pain patients: a literature review. *Eur J Pain.* 2007; 11:490-518.
25. Ward SE, Goldberg N, Miller-McCauley V, et al. Patient-related barriers to management of cancer pain. *Pain.* 1993;52:319-324.
26. Koffman J, Burke G, Dias A, et al. Demographic factors and awareness of palliative care and related services. *Palliat Med.* 2007;21:145-153.
27. Kuin A, Courtens AM, Deliens L, et al. Palliative care consultation in the Netherlands: a nationwide evaluation study. *J Pain Symptom Manage.* 2004;27: 53-60.
28. Morita T, Hirai K, Sakaguchi Y, Maeyama E, Tsuneto S, Shima Y. Measuring the quality of structure and process in end-of-life care from the bereaved family perspective. *J Pain Symptom Manage.* 2004;27: 492-501.

Original Article

Symptom Prevalence and Longitudinal Follow-Up in Cancer Outpatients Receiving Chemotherapy

Akemi Yamagishi, RN, MNS, Tatsuya Morita, MD, Mitsunori Miyashita, RN, PhD, and Fukuko Kimura, MD, PhD

Japan Cancer Society (A.Y.), Tokyo; Department of Adult Nursing/Palliative Care Nursing (A.Y., M.M.), School of Health Sciences and Nursing, Graduate School of Medicine, The University of Tokyo, Tokyo; Department of Palliative and Supportive Care, Palliative Care Team and Seirei Hospice (T.M.), Seirei Mikatabara Hospital, Hamamatsu; and International University of Health and Welfare (A.Y., F.K.), Tokyo, Japan

Abstract

Palliative care for cancer patients receiving chemotherapy in the outpatient setting is important. The aims of this study were 1) to identify symptom prevalence and intensity in cancer patients receiving chemotherapy and 2) to describe longitudinal follow-up data obtained from repeated assessment using the distress thermometer (DT). Questionnaires were distributed to consecutive cancer outpatients newly starting chemotherapy at the first appointment and at every hospital visit. The questionnaire included the severity of 11 symptoms (M. D. Anderson Symptom Inventory [MDASI], Japanese version), the DT, and the need for help in four psychosocial areas (decision-making, economic problems, nutrition, and daily activities). In total, 4000 questionnaires were returned by 462 patients. The frequently identified problems were oral problems (21%), insomnia (19%), psychological distress (defined as the DT score of 6 or more; 15%), help with information and decision-making (14%), severe fatigue (8.2%), and severe appetite loss (6.3%). Cluster analysis identified four symptom clusters: 1) fatigue and somnolence; 2) pain, dyspnea, and numbness; 3) nausea, appetite loss, and constipation; and 4) psychological distress. Of 165 patients with a DT of score 6 or more, 115 patients (70%) demonstrated a DT score below 6 at a median of 17 days' follow-up. In the remaining 50 patients who had a DT score of 6 or more at follow-up, 34 patients (68%) had one or more physical symptoms rated at 7 or more on an 11-point numeric rating scale. Compared with patients with a DT score below 6 at follow-up, patients with a DT score of 6 or more at follow-up had higher levels of all physical symptoms. Frequent symptoms experienced by cancer outpatients receiving chemotherapy may be categorized as: 1) psychosocial issues (insomnia, psychological distress, decision-making support); 2) nutrition-gastrointestinal issues (oral problems, appetite loss, nausea); 3) fatigue; and 4) pain, dyspnea, and numbness. Developing a systematic intervention program targeting these four areas is urgently required. The DT score may be highly influenced by coexisting physical symptoms, and future studies to develop an appropriate

This study is supported by the Sasakawa Health Science Foundation.

Address correspondence to: Tatsuya Morita, MD, Palliative Care Team and Seirei Hospice, Seirei

Mikatabara Hospital, 3453 Mikatabara-cho, Hamamatsu, Shizuoka 433-8558, Japan E-mail: tmorita@sis.seirei.or.jp

Accepted for publication: April 6, 2008.

system to identify patients with psychiatric comorbidity are necessary. *J Pain Symptom Manage* 2008;■:■-■. © 2008 U.S. Cancer Pain Relief Committee. Published by Elsevier Inc. All rights reserved.

Key Words

Palliative care, neoplasms, chemotherapy, outpatient

Introduction

Increasing numbers of cancer patients receive chemotherapy in the outpatient setting,¹ and symptom palliation for these outpatients is urgently required. The recent literature suggests a broad range of palliative care needs, including physical symptoms, psychological distress, help with decision-making, and economical and practical support.²⁻⁷

Knowledge of symptom prevalence is important in clinical practice: 1) to anticipate problems and needs of patients; 2) to plan care for patients; and 3) to educate clinical staff to focus on particular symptoms.⁸ To clarify symptom prevalence and understanding patient needs are the first steps to establish an effective palliative care system for patients.

Although many studies have addressed symptom prevalence in cancer patients, their findings may not generalize to cancer outpatients receiving chemotherapy, because: 1) most studies include cancer patients receiving no anticancer treatments,⁹⁻¹⁵ and few have specifically addressed cancer patients receiving chemotherapy; 2) sample sizes are usually small and nonrepresentative (i.e., limited to a certain specialty or patients consenting to a research intervention); and 3) no systematic survey has been performed in Japanese patients. In addition, cancer patients often have multiple concurrent symptoms,¹⁴⁻¹⁸ and symptom management has shifted from individual symptoms to symptom clusters,¹⁹⁻²¹ but a few empirical studies have examined clustering symptoms in outpatient cancer patients receiving chemotherapy. To address these limitations, the first aims of this study were 1) to clarify the prevalence of physical and psychological symptoms and concerns among a representative sample of cancer patients receiving chemotherapy in the outpatient setting and 2) to evaluate symptom clusters in this study population.

One of the most important symptoms is psychiatric comorbidity, including major depression and adjustment disorders. Despite the importance of early diagnosis and treatment, psychiatric comorbidity is difficult to identify and is often overlooked.^{22,23} Recent empirical studies suggested that the distress thermometer (DT) can be an appropriate method to identify cancer patients with major depression and adjustment disorder.²⁴⁻²⁷ The study populations in these studies, however, were limited to cancer patients referred to a psychiatric consultation service or a palliative care unit, or awaiting bone marrow transplantation, and only cross-sectional assessments were obtained. Longitudinal data from the outpatient chemotherapy setting, where the patient often experiences short-term deterioration and improvement of physical symptoms related to chemotherapy, are lacking. Clarifying longitudinal changes and the effects of physical symptoms on the DT can contribute to better understanding of the DT as a tool to identify psychiatric comorbidity in outpatient chemotherapy settings. The second aim of this study was thus to explore longitudinal change and the effects of physical symptoms on the DT.

Patients and Methods

This study included all cancer patients newly starting chemotherapy, with primary tumor sites of the lung, stomach or intestine, pancreas, bile duct, breast, ovary, and uterus from April 2006 to December 2007. At the appointment regarding chemotherapy, pharmacists handed out a self-report questionnaire, with coaching on how to complete it.²⁸ This intervention was part of general instruction for outpatient chemotherapy, and required 10 to 20 minutes for completion. All pharmacists received an hour of educational instruction by the second author. Questionnaires were

thereafter distributed at every hospital visit. If the patients refused to complete the questionnaire or recognized no need, they were not obliged to complete it.

Demographic and medical variables (age, sex, primary cancer site, and opioid consumption) were obtained from medical charts. Opioid consumption was calculated as the daily amounts (mg) of oral morphine using the standard calculation ratio (transdermal fentanyl, 25 µg/hour = oral oxycodone, 40 mg = oral morphine, 60 mg).

The Institutional Review Board approved the ethical and scientific validity of a retrospective analysis of the questionnaire data obtained as part of routine clinical activity. Admitted patients gave written consent that their clinical information could be used for clinical research.

Questionnaire

The study group developed the questionnaire on the basis of existing validated instruments^{24,29-32} (available in our previous report²⁸). The questionnaire included 1) an open-ended question about the patient's greatest concerns; 2) 0-10 numeric rating scales of eight physical symptoms (pain, dyspnea, nausea, appetite loss, somnolence, fatigue, constipation, numbness) adopted from the Japanese version of the M. D. Anderson Symptom Inventory (MDASI)²⁹; 3) presence or absence of oral problems, fever, and insomnia; 4) a 0-7 numeric rating scale of overall quality of life adopted from item 29 of the European Organization for Research and Treatment of Cancer (EORTC)-C30 questionnaire³⁰; 5) the DT^{24,31}; 6) presence or absence of a need for help in four areas, i.e., information about treatment and decision-making, economic problems, nutrition, and daily activities^{7,32}; wish for help from the specialized palliative care service.

Analyses

The prevalence of problems was calculated for each questionnaire. Analyses of opioid consumption were performed only for patients receiving opioids. For calculations, we adopted the definition of moderate and severe symptom intensity for MDASI items as 4-6 and 7-10, respectively. We used cutoff points on the DT of 6 or more based on previous findings,^{24,31} and follow-up data of the DT was

defined as the score obtained at a visit closest to two weeks after the initial assessment and within four weeks. We determined that a patient had problems if s/he had MDASI symptoms score as 7 or more, an oral problem, fever, insomnia, a DT score of 6 or more, or an expressed need for any help with information and decision-making, nutrition, economic problems, or daily activities.

For comparisons, age was classified into two groups (less than 60 and 60 or more years), and primary tumor sites were classified into three groups (chest, breast, and gastrointestinal). Univariate analysis was performed by the Mann-Whitney test or Kruskal-Wallis test, where appropriate. The effect of age was estimated with adjustment for gender and primary tumor site, and the effect of gender was estimated with adjustment for age and primary tumor site.

We performed cluster analysis and displayed a dendrogram using average linkage. Clusters were formed based on the distance between symptom ratings, which were calculated using squared Euclidian distances.

To explore the longitudinal change and effects of physical symptom on the DT, we initially identified all patients who had a DT score of 6 or more at any time during the study period. We then classified them into two groups: those with a DT score that declined to less than 6 at the follow-up and those with a DT score of 6 or more at the follow-up. We compared their demographic factors and the intensity of all physical symptoms.

For statistical analysis, SPSS for Windows (version 11.0) was used.

Results

During this study period, 472 patients newly started chemotherapy, and 10 refused to complete the questionnaire. In total, we obtained 4000 questionnaires from 462 patients (compliance rate, 98%). Each patient completed a median of six questionnaires during the study period. The percentages of missing values ranged from 2.8% (appetite loss) to 4.8% (dyspnea). Table 1 summarizes the patient characteristics. Forty-seven patients received opioid, with a mean of 36 mg oral morphine equivalent/day (range, 5.0-170;