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Original Article

Treatment Efficacy of Neural Blockade
in Specialized Palliative Care Services
in Japan: A Multicenter Audit Survey

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Abstract

More than 85% of cancer-related pain is pharmacologically controllable, but some patients require interventional treatments. Although audit assessment of these interventions is of importance to clarify the types of patients likely to receive benefits, there have been no multicenter studies in Japan. The primary aims of this study were (1) to clarify the frequency of neural blockade in certified palliative care units and palliative care teams, (2) determine the efficacy of interventions, and (3) explore the predictors of successful or unsuccessful intervention. All patients who received neural blockade were consecutively recruited from seven certified palliative care units and five hospital palliative care teams in Japan. Primary responsible physicians reported pain intensity on the Support Team Assessment Schedule, performance status, communication levels on the Communication Capacity Scale, presence or absence of delirium, opioid consumption, and adverse effects before and one week after the procedure on the basis of retrospective chart review. A total of 162 interventions in 136 patients were obtained, comprising 3.8% of all patients receiving specialized palliative care services during the study period. Common procedures were epidural nerve block with local anesthetic and/or opioids ($n = 84$), neurolytic sympathetic plexus block ($n = 24$), and intrathecal nerve block with phenol ($n = 21$). There were significant differences in the frequency of neural blockade between palliative care units and palliative care teams (3.1% vs. 4.6%, respectively, $P = 0.018$), and between institutions whose leading physicians are

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anesthesiologists or have other specialties (4.8% vs. 1.5%, respectively, $P < 0.001$). Pain intensity measured on the Support Team Assessment Schedule (2.9 ± 0.8 to 1.7 ± 0.9 , $P < 0.001$), performance status (2.7 ± 1.0 to 2.4 ± 1.0 , $P < 0.001$), and opioid consumption (248 ± 348 to 186 ± 288 mg morphine equivalent/day, $P < 0.001$) were significantly improved after interventions. There was a tendency toward improvement in the communication level measured on the Communication Capacity Scale. There was no significant improvement in the prevalence of delirium, but six patients (32%) recovered from delirium after interventions. Adverse effects occurred in 9.2%, but all were predictable or transient. No fatal complications were reported. Pain intensity was significantly more improved in patients who survived 28 days or longer than others ($P = 0.002$). There were no significant correlations of changes in pain intensity with the performance status or previous opioid consumption. In conclusion, neural blockade was performed in 3.8% of cancer patients who received specialized palliative care services in Japan. Neural blockade could contribute to the improvement of pain intensity, performance service status, and opioid consumption without unpredictable serious side effects. *J Pain Symptom Manage* 2008;36:461–467. © 2008 U.S. Cancer Pain Relief Committee. Published by Elsevier Inc. All rights reserved.

Key Words

Neural blockade, pain, neoplasm, palliative care

Introduction

Pain is one of the most common complications in cancer patients, and it significantly impairs their quality of life. Empirical studies have demonstrated that more than 85% of cancer-related pain is pharmacologically controllable, but the remaining patients require a multidisciplinary approach.^{1–4} As part of this multidisciplinary approach, many empirical studies have revealed the efficacy of neural blockade in cancer pain management refractory to standard pharmacological treatments.^{5–15} Audit assessment of interventional treatment is of importance to improve patients' quality of life by clarifying the types of patients likely to receive benefits. In Japan, however, no multicenter studies to date have investigated how frequently neural blockade is used in oncology or specialized palliative care settings; the efficacy and the predictors of successful interventions have not been evaluated. Therefore, as a preliminary study to develop a prospective audit registry system of neural blockade, we conducted this study with the primary aims: (1) to clarify the frequency of neural blockade in certified palliative care units and palliative care teams, (2)

(3) explore the predictors of successful or unsuccessful intervention.

Patients and Methods

The study participants were consecutively recruited from the participating institutions. The inclusion criteria were adult cancer patients who required neural blockade to manage pain refractory to standard pharmacological management. The participating institutions were seven certified palliative care units and five hospital palliative care teams across the country, conveniently selected from 120 certified palliative care units and 20 palliative care teams where coresearchers were available. Due to the preliminary nature of this study and practical difficulties, we made no effort to enroll a representative sample of all specialized palliative care services in Japan. The institution researchers were requested to report all patients who received neural blockade for pain control in 2002–2003. For each patient, they reported pain intensity, performance status, communication levels, presence or absence of delirium, opioid consumption, and any adverse effects before and one week after the intervention on the basis of retrospective chart review. We used a structured data-collecting

sheet and standardized rating protocols to maximize the reliability.

Measurements

The degree of pain was evaluated using the Japanese version of the Support Team Assessment Schedule.¹⁶ Performance status was graded with reference to the ECOG Performance Status. The degree of communication was measured as Item 4 on the Communication Capacity Scale, originally a validated five-item observer-rating scale used to quantify communication capacity in terminally ill patients (Appendix).¹⁷ This item rated the degree of patients' capacity to achieve clear communication on a scale of 0–3, with a score of 0 or 1 indicating that the patient can achieve clear communication of complex or simple content, respectively. Delirium was diagnosed following the Diagnostic and Statistical Manual-IV. Retrospective grading using these scales achieved fair interrater reliability in previous studies.^{18,19} The total opioid dose was defined as the total amount of oral morphine equivalent following a standard ratio.²⁰

Statistical Analysis

Pre–post comparisons were performed with the paired Student's *t*-test or McNamara test, where appropriate. To explore the predictors of treatment success, we compared the changes in pain intensity between subgroups: patients with a performance status before intervention ≤ 2 ($n = 59$) vs. ≥ 3 ($n = 96$); patients who survived 28 days or longer ($n = 85$) vs. less than 28 days ($n = 27$); patients receiving more than 120 mg oral equivalent of morphine per day ($n = 66$) vs. others ($n = 89$), using two-way repeated-measures analysis of variance.

All analyses were performed using the Statistical Package for the Social Sciences (version 11.5).

Results

We obtained data on 162 interventions for 136 patients who required neural blockade during the study period. Eighteen patients received two procedures, and four patients received three procedures.

Table 1 shows the demographic characteristics of the patients. The main primary cancers were colorectal, gynecologic, and pancreatic.

Table 1
Patient Background ($n = 136$)

	% (n)
Mean age (years)	59 ± 15
Gender	
Male	63 (85)
Female	37 (51)
Performance status	2.7 ± 1.0
Mean survival (days)	103 ± 105 (median 67)
Treatment setting	
Palliative care units	43 (58)
Palliative care teams	57 (78)
Primary tumor site	
Colon, rectum	35 (47)
Uterus, ovary	14 (19)
Pancreas	13 (18)
Prostate, kidney, bladder	8.1 (11)
Lung	7.4 (10)
Liver, gallbladder, bile duct	5.1 (7)
Head and neck	3.7 (5)
Stomach	2.9 (4)
Breast	2.9 (4)
Esophagus	2.2 (3)
Soft tissue	2.2 (3)
Blood	2.2 (3)
Bone	1.4 (2)

Table 2 summarizes the procedures and pain characteristics. Common procedures were epidural nerve block with local anesthetics and/or opioids, neurolytic sympathetic plexus block, and intrathecal nerve block with phenol. Epidural block was temporary in 11 patients, and the median duration of placement was 22 days.

Frequency and Institution Differences

The total number of patients receiving specialized palliative care services during the study period was 3,553; thus, 3.8% of patients underwent procedures. The percentage ranged from 0.6% to 15% (median, 4.5%) among the 12 participating institutions. There were significant differences in the frequency of neural blockade between palliative care units and palliative care teams (3.1% vs. 4.6%, respectively, $P = 0.018$), and between institutions whose leading physicians are anesthesiologists or have other specialties (4.8% vs. 1.5%, respectively, $P < 0.001$).

Treatment Efficacy and Safety

Overall, pain intensity measured on the Support Team Assessment Schedule, performance status, and opioid consumption were significantly improved after neural blockade (Table 3). Opioid consumption fell 30% or more in 33% of the patients ($n = 43$). In addition, there was

Table 2
Procedure and Pain Characteristics
(n = 162 Interventions)

	% (n)
Procedures	
Epidural nerve block with local anesthetics and/or opioids	52 (84)
Sympathetic plexus block	15 (24)
Intrathecal nerve block with phenol	13 (21)
Peripheral nerve block	6.8 (11)
Epidural nerve block with phenol	5.6 (9)
Intrathecal nerve block with local anesthetics	1.9 (3)
Trigeminal nerve block	1.9 (3)
Selective root block	1.9 (3)
Impair ganglion block	1.2 (2)
Stellate ganglion block	1.2 (2)
Pain characteristics	
Location	
Hip, perineum, anus	30 (57)
Lower extremity	18 (34)
Abdomen	17 (32)
Lumbar, back	14 (27)
Chest	12 (22)
Shoulder, upper extremity	5.3 (10)
Head, neck	4.2 (8)
Etiology	
Cancer-related	83 (135)
Procedure-related	8.6 (14)
Benign	8.0 (13)
Characteristics	
Somatic	34 (55)
Visceral	20 (33)
Somatic and neuropathic	15 (24)
Neuropathic	14 (22)
Somatic and visceral	12 (19)
Somatic and visceral and neuropathic	3.1 (5)
Visceral and neuropathic	2.5 (4)

a tendency toward improvement in the communication levels measured on the Communication Capacity Scale, although the difference did not reach significance.

On the other hand, there was no significant improvement in the prevalence of delirium. In 19 patients with delirium, however, six patients (32%) recovered after interventions.

By subgroup analyses (i.e., epidural analgesia, neurolytic sympathetic plexus block, and intrathecal neurolytic analgesia), pain intensity was significantly improved after interventions in all subgroups (Table 4). There was no significant improvement in the communication level or prevalence of delirium. The performance status was significantly improved in the subgroups of patients receiving epidural analgesia and sympathetic plexus block, but not in those receiving intrathecal neurolytic analgesia. Opioid consumption significantly decreased in patients receiving epidural analgesia and intrathecal neurolytic analgesia, but not in those receiving sympathetic plexus block.

Safety

Adverse effects occurred in 15 of 162 procedures (9.2%) (Table 5). Detrusor sphincter dyssynergia occurred after intrathecal nerve block, although this was a predictable and informed complication in all cases. Other complications were transient, and no fatal event was reported.

Predictors of Successful Treatment

Pain intensity was significantly more improved in patients who survived 28 days or longer than others (Fig. 1, $P = 0.002$). There were no significant differences in the changes in pain intensity between patients with a performance status ≤ 2 vs. those ≥ 3 , and patients receiving more than 120 mg oral equivalent of morphine per day vs. others (data not shown).

Table 3
Overall Treatment Efficacy (n = 162 Interventions)

	Before	One Week After	P
Pain ^a	2.9 ± 0.8	1.7 ± 0.9	<0.001
Severe (≥ 3)	68% (n = 110)	19% (n = 31)	
Performance status	2.7 ± 1.0	2.4 ± 1.0	<0.001
3 or 4	59% (n = 96)	46% (n = 74)	
Communication capacity ^b	0.31 ± 0.67	0.26 ± 0.62	0.083
No clear communication	9.9% (n = 16)	8.0% (n = 13)	
Delirium	12% (n = 19)	11% (n = 18)	1.0
Opioid consumption (mg/day) ^c	248 ± 348	186 ± 288	<0.001

^aEvaluated using the Support Team Assessment Schedule over the range of 0-4. A higher score indicates a greater level of pain intensity.

^bMeasured as Item 4 on the Communication Capacity Scale over the range of 0-3. A higher score indicates a greater level of communication impairment. No clear communication was defined as a score of 2 or 3.

^cCalculated as the total amount of oral morphine equivalent to a daily dose.

Table 4
Treatment Efficacy of Each Procedure

	Before	One Week After	P
Epidural nerve block with local anesthetics and/or opioids			
Pain ^a	3.0 ± 0.9	1.7 ± 0.9	<0.001
Severe (≥3)	73% (n = 58)	57% (n = 45)	
Performance status	2.8 ± 1.1	2.6 ± 1.0	<0.001
3 or 4	68% (n = 54)	56% (n = 44)	
Communication capacity ^b	0.2 ± 0.5	0.2 ± 0.5	0.32
No clear communication	6.3% (n = 5)	6.3% (n = 5)	
Delirium	6.3% (n = 5)	8.9% (n = 7)	0.69
Opioid consumption (mg/day) ^c	210 ± 298	162 ± 258	<0.001
Sympathetic plexus block			
Pain ^a	2.6 ± 0.9	1.7 ± 0.9	0.03
Severe (≥3)	52% (n = 12)	13% (n = 3)	
Performance status	2.2 ± 0.8	1.9 ± 0.8	<0.01
3 or 4	39% (n = 9)	30% (n = 7)	
Communication capacity ^b	0.1 ± 0.5	0.04 ± 0.2	0.16
No clear communication	4.3% (n = 1)	0% (n = 0)	
Delirium	8.7% (n = 2)	0% (n = 0)	—
Opioid consumption (mg/day) ^c	277 ± 319	246 ± 326	0.27
Intrathecal nerve block with phenol			
Pain ^a	2.7 ± 0.7	1.5 ± 0.9	<0.001
Severe (≥3)	68% (n = 13)	47% (n = 9)	
Performance status	2.8 ± 0.8	2.6 ± 0.9	0.16
3 or 4	68% (n = 13)	47% (n = 9)	
Communication capacity ^b	0.6 ± 0.8	0.4 ± 0.7	0.19
No clear communication	21% (n = 4)	11% (n = 2)	
Delirium	26% (n = 5)	16% (n = 3)	0.50
Opioid consumption (mg/day) ^c	452 ± 588	295 ± 419	0.014

^aEvaluated using the Support Team Assessment Schedule over the range of 0–4. A higher score indicates a greater level of pain intensity.

^bMeasured as item 4 on the Communication Capacity Scale over the range of 0–3. A higher score indicates a greater level of communication impairment. No clear communication was defined as a score of 2 or 3.

^cCalculated as the total amount of oral morphine equivalent to a daily dose.

Discussion

This is the first multicenter study to assess the clinical utility of neural blockade in specialized palliative care services in Japan. One important finding is the clarification of the frequency of neural blockade in certified palliative care units and palliative care teams. In this study, 3.8% of patients receiving specialized palliative care services required neural blockade for acceptable pain control. This figure is generally close to the previous findings in Western countries,^{1–4} and suggests that some cancer patients require

interventional pain treatment to achieve maximum balanced analgesia. Specialized palliative care patients should thus have open access to pain specialists who can provide these interventions. Of special note was a significant, although modest, difference in the frequency of neural blockade among institutions: the treatment setting (palliative care units vs. teams) and the specialty of leading physicians. This indicates the strong need for explicit referral criteria for interventional pain treatment to maximize the appropriate referral of potentially benefiting patients.

The second and most important finding of this study is clarification of the efficacy and safety of these interventions. This study suggests that neural blockade can improve pain intensity, performance status, and opioid consumption without unpredictable serious adverse effects. This finding is consistent with previous studies,^{5–11} and strongly supports the clinical utility of neural blockade in carefully selected patient refractory to standard pharmacological pain management.

Table 5
Adverse Effects

	n (%)
Detrusor sphincter dyssynergia	5 (3.1)
Hypotension	3 (1.9)
Back pain	2 (1.2)
Transitory motor weakness	1 (0.6)
Infection	1 (0.6)
Respiratory depression	1 (0.6)
Headache	1 (0.6)
Acute alcoholism	1 (0.6)

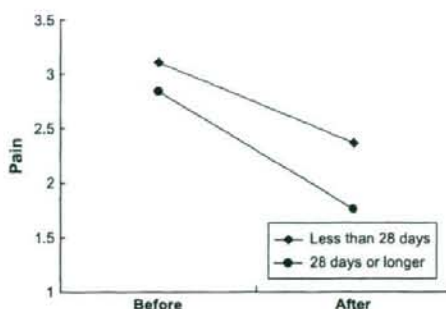


Fig. 1. Changes in pain intensity between patients surviving 28 days or longer vs. less than 28 days.

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.

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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

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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

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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.

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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.

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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

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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

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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