

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

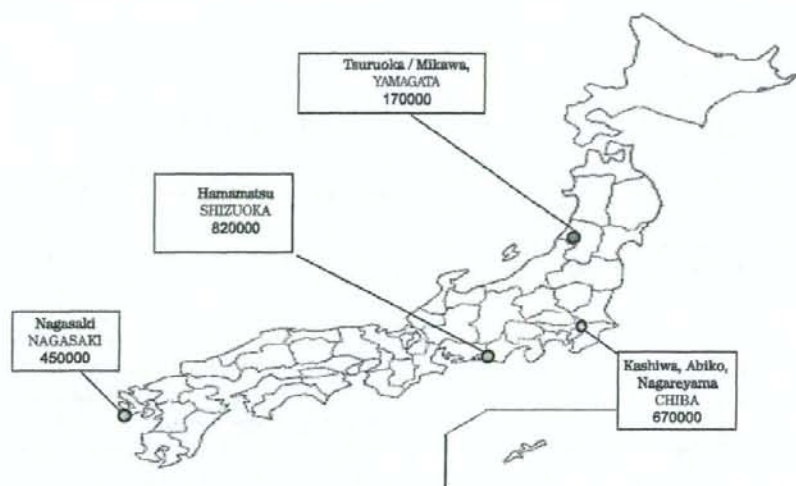


Figure 1. Participating areas of the Outreach Palliative Care Trial of Integrated Regional Model (OPTIM) study are shown with the resident population number.

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 Kanwaka Hakuho* [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. *Kokumineiseinodoukou 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.dhtk.mhlw.go.jp/toukei/data/010/2005/toukeiyou/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.

Measuring the regret of bereaved family members regarding the decision to admit cancer patients to palliative care units

M. Shiozaki^{1*}, K. Hirai², R. Dohke³, T. Morita⁴, M. Miyashita⁵, K. Sato⁵, S. Tsuneto⁶, Y. Shima⁷ and Y. Uchitomi⁸

¹Research Fellow of the Japan Society for the Promotion of Sciences, and Public Health, Graduate School of Medicine, Osaka University, Osaka, Japan

²Center of the Study for Communication Design, Psychology and Behavioral Sciences, Graduate School of Human Sciences, and Department of Complementary and Alternative Medicine, Graduate School of Medicine, Osaka University, Osaka, Japan

³Department, Graduate School of Social Sciences, Hitotsubashi University, Tokyo, Japan

⁴Department of Palliative and Supportive Care, Palliative Care Team and Seirei Hospice, Seirei Mikatahara Hospital, Shizuoka, Japan

⁵Department of Adult Nursing/Palliative Care Nursing, School of Health Sciences and Nursing, Graduate School of Medicine, Tokyo University, Tokyo, Japan

⁶Department of Palliative Medicine, Graduate School of Medicine, Osaka University, Osaka, Japan

⁷Department of Palliative Medicine, Tsukuba Medical Center Hospital, Ibaraki, Japan

⁸Psycho-Oncology Division, Research Center for Innovative Oncology, National Cancer Center Hospital East, Chiba, Japan

*Correspondence to: Graduate School of Medicine, Public Health, Osaka University, Suita, Osaka, Japan. E-mail: mariko@nira.hus.osaka-u.ac.jp

Abstract

Objective: The purposes of this study were to develop a bereaved family regret scale measuring decision-related regret of family members about the admission of cancer patients to palliative care units (PCUs) and to examine the validity and reliability of this scale.

Method: Bereaved families of cancer patients who had died in one regional cancer center from September 2004 to February 2006 received a cross-sectional questionnaire by mail. The questionnaire contained seven items pertaining to decision-related regret about the patient's admission to the PCU, the Care Evaluation Scale (CES), an overall care satisfaction scale, and a health-related quality-of-life (QOL) scale (SF-8). One month after receiving a completed questionnaire, we conducted a retest with the respondent.

Results: Of the 216 questionnaires successfully mailed to the bereaved families, we received 137 questionnaires and were able to analyze the responses for 127 of them, as the other 10 had missing data. By exploratory factor analysis and confirmatory factor analysis, we identified two key factors: intrusive thoughts of regret and decisional regret. This scale had sufficient convergent validity with CES, overall care satisfaction, SF-8, sufficient internal consistency, and acceptable test-retest reliability.

Conclusion: We have developed and validated a new regret scale for bereaved family members, which can measure their intensity of regret and their self-evaluation about their decision to admit their loved ones to PCUs.

Copyright © 2007 John Wiley & Sons, Ltd.

Keywords: regret; the bereaved family; decision-making; cancer; oncology

Received: 10 May 2007
Revised: 24 October 2007
Accepted: 31 October 2007

Introduction

Researchers into end-of-life issues have recognized the value of what they have called a 'good death'. Critical to achieving a 'good death' is the 'completion of life,' which entails one's being prepared for dying, a feeling that one's life has been completed, no regrets about one's death, and family members who also have no regrets about one's death. Thus, minimizing the regret of cancer patients and their families is an important issue for achieving a 'good death' [1, 2]. However, bereaved

family members who have lost a loved one may find themselves experiencing self-blame feelings of regret along the lines of, 'I may have had to do it for my loved one' or 'I may not have had to do it for my loved one' [3].

Such feelings are a component of regret, the painful sensation that can result from recognizing that 'what is' compares unfavorably with 'what might have been' [4]. Early regret studies have found that a bad outcome resulting from action seemed more regrettable than the same bad outcome resulting from inaction [5] and that regretta-

ble feelings may exhibit a temporal reversal, with action evoking more regret in the short term and inaction evoking more regret in the longer term [6]. Subsequent research has categorized regrets in the daily decision context into three types according to their target: outcome regret, option regret, and process regret [7]. For each of these regret types, researchers have examined the effects of anticipated regret on decision-making as well as the effect of decision-making on experienced regret. Investigators have explored various theories and models to try to explain decision-related regret. Connolly and Zeelenberg, for instance, have recently proposed a new model called decision justification theory (DJT) [8]. DJT postulates two core components of decision-related regret: evaluation of the outcome and the feeling of self-blame for having made a poor choice. The overall feeling of regret at the decision is the combination of these two components. Thus DJT might offer a new explanation as to how people still feel regret even when they experience a situation in which the actual outcome is good. In contrast, most regret studies to date have evaluated regret by examining either the past decision or the self-blame feeling.

With respect to cancer patients, regret studies have typically focused on fatal decisions regarding what course of treatment to follow, e.g. [9] or whether to undergo a screening test [10]. Several studies of prostate cancer patients have established that patients can feel substantial regret following their cancer-related fatal decisions [11–13] and that such treatment-related regret is associated with worse current health-related quality of life (QOL) [11] and with worse quality of life and emotional well-being [12]. Future research should further explore how aspects of the fatal decision process affect later regret in cancer patients and their families.

Family members will face various decisions as well as the cancer patients themselves during the course of illness. However, no reports are available regarding decision-related irremediable regret among family members within bereaved families. Cohesiveness and control are much greater within Japanese than within western families [14]. Also, the opinions of family members tend to exert greater influence on clinical decision-making in Japan than in the United States [15, 16]. The assessment of current irremediable regret can retrospectively color past decision-making processes. Current irremediable regret also can strongly affect future psychological status. Developing a vigilant decision-making model focused on the regret of bereaved family could help provide useful information for improving decision-making by cancer patients and their families. One important area of decision-making for cancer patients and their families involves the decision process by which physicians

initially refer patients to palliative care units (PCUs) [17]. This study thus endeavored to develop a bereaved family regret scale measuring irremediable regret regarding the decision to admit cancer patients into PCUs and to examine the validity and reliability of this scale.

Methods

Participants and procedure

Our initial set of potential study participants comprised family members of patients who had died from September 2004 to February 2006 in Ibaraki prefecture, Japan. Inclusion criteria were as follows: the patient had died in a PCU; the patient was 20 years of age or older; and the patient had been admitted to the PCU at least three days prior to death. Exclusion criteria were as follows: the family member participant had already been recruited for another questionnaire survey for bereaved family members; the family member's primary physician determined that the participant would suffer serious psychological distress from participation in the study; the patient's cause of death was either directly treatment related or secondary to a treatment-related injury; or no member of the bereaved family was 20 years of age or older, capable of replying to a self-reported questionnaire, or aware of the patient's diagnosis of malignancy.

We mailed questionnaires to potential respondents in October 2006 and mailed reminders in November 2006 to those who had not responded. We asked respondents who did not wish to participate in the survey to indicate that they did not wish to participate and to return the questionnaire. To examine test-retest reliability, we sent a follow-up questionnaire one month after we received a completed questionnaire. The institutional review boards of Tsukuba Medical Center Hospital approved the ethical and scientific validity of this study.

Of the 224 questionnaires sent to eligible bereaved families, eight were undeliverable. We received 137 of the remaining 216 questionnaires, among which we had to exclude 10 due to missing data. Thus, we analyzed 127 responses (effective response rate, 59%). Among these 127 respondents who submitted analyzable test questionnaires, we sent retest questionnaires to the 121 bereaved families who responded during the study period; the other six families submitted their test responses too late to be included in the retest program. We received 82 retest questionnaires, among which we excluded 11 due to missing data. In total, we analyzed 71 retest questionnaires (effective response rate, 59%).

Measures

Decision-related regret about admission to PCUs

The questionnaires asked participants to rate on a 5-point self-reported Likert scale (strongly disagree–strongly agree) their level of agreement with each of seven possible regrets that they may have experienced regarding their decision-making in the past about admitting their loved ones to a PCU. Most previous studies have evaluated regret only for single statements, such as 'how do you feel regret concerning XX'. In addition, we collected from prior studies three statements measuring the evaluation of decisions in the past [11, 18] and three other statements measuring severity and intensity of regret [19]. The evaluation-of-decision statements included, 'I made the right decision' and 'I would make the same decision if I had to do it again'. The severity and intensity of regret statements included, 'Once I start thinking about possible outcomes had I made a different decision, I find it difficult to think about other matters' and 'I had difficulty concentrating on daily activities because thoughts about regret kept entering my mind'. We constructed the wording of these statements based upon the palliative physicians' and psychologists' comments regarding understandability and wording.

Care evaluation scale, short version

We used the Care Evaluation Scale (CES), short version, to examine concurrent validity [20]. The questionnaire design has the respondent evaluating the necessity of improvement for each item on a 6-point Likert scale (improvement is not necessary–highly necessary). The short version of CES used in this study comprises 10 items covering the following 10 domains: help with decision-making for patient, help with decision-making for family, physical care by physician, physical care by nurse, psycho-existential care, environment, cost, availability, coordination of care, and family burden.

Overall care satisfaction

We assessed overall care satisfaction as part of our examination of concurrent validity by asking the following question, developed in a previous study [21]: 'Overall, were you satisfied with the care provided in the hospital?' The participant again responded on a 6-point Likert scale.

Health-related QOL

We used the SF-8 Japanese version [22], the short form, which is derived from the health-related QOL scale called the MOS 36-Item Short Form Health Survey (SF-36). The eight items cover the eight concepts measured by the SF-36 (one item per concept), using a 5- or 6-point Likert scale. The

SF-8 provides two summary scores for physical and mental health: a Physical Component Scale and a Mental Component Scale. Scores for each item and summary measurements range from 0 to 100, with higher scores indicating better health. This scale includes questions such as the following: 'Overall, how would you rate your health during the past 4 weeks'; 'During the past 4 weeks, how much did physical health problems limit your usual physical activities (such as walking or climbing stairs)'; and 'During the past 4 weeks, how much difficulty did you have doing your daily work, both at home and away from home, because of your physical health?'

Participant characteristics

We extracted information concerning the patient's age, sex, and hospital days from a medical database. We asked the respondent bereaved family members to provide the following personal information about themselves: age, sex, health status during caregiving period, relationship with patient, frequency of attending the patient, presence of other caregivers, living status with patient, faith, education, and household income during the caregiving period.

Analysis

We utilized the Statistical Package for SPSS for Windows (Version 14.0) for all data analyses. To examine validity of our regret scale, we conducted an exploratory and a confirmatory factor analysis along with correlation analyses of our regret scale vs CES, overall satisfaction, and QOL. To examine the reliability of the regret scale, we assessed the internal reliability of its two subscales with Cronbach's α coefficients. We used correlation coefficients to assess test–retest reliability.

Results

Characteristics of participants

Table 1 shows the demographic characteristics of the 127 participants included in the development analysis. We compared the demographic characteristics of these 127 participants with those of the 71 participants included in the validation analysis. We identified no significant differences between the two groups with respect to all demographic characteristics. Table 1 also shows descriptive statistics of decision-related regret, CES, overall satisfaction, and health-related QOL.

Validity

All of the seven items had a moderate degree of variance, and no item evidenced bias. Using these

Table 1. Characteristics of the bereaved family and patient

	N = 127 Patient numbers or mean \pm SD	%
Bereaved family		
Age	55.85 \pm 12.11	
Sex, male	44	34.6
Health status during caregiving period		
Good	33	26
Somewhat good	71	55.9
Bad	20	15.7
Strongly bad	2	1.6
Relationship to patient		
Spouse	61	48
Parent	42	33.1
Parent-in-law	13	10.2
Others	10	7.9
Frequency of attending patient		
Everyday	96	75.6
4-6 days/week	11	8.7
1-3 days/week	15	11.8
None	3	2.4
Presence of other caregivers		
Living with patient	89	70.1
	106	83.5
Education		
Less than high school	17	13.4
High school	56	44.1
Some college	28	22
Postgraduate	25	19.7
Household income during caregiving period		
Less than 250	13	10.2
250-500	58	45.7
500-750	25	19.7
750-1000	14	11
More than 1000	14	11
Care Evaluation Scale	75.49 \pm 17.63	
Overall satisfaction	4.76 \pm 0.96	
SF8; Physical Component Scale	48.78 \pm 7.81	
SF8; Mental Component Scale	48.52 \pm 6.37	
Patient		
Age	68.12 \pm 12.28	
Sex, male	68	53.5
Hospital days	41.63 \pm 33.90	

seven items, we conducted an exploratory factor analysis with promax rotation and the maximum-likelihood method. A minimal eigenvalue >1 yielded a 2-factor solution (Table 2), in which these two factors explained 74% of the variance. The correlation coefficient between the two factors was 0.32 ($p < 0.01$). Factor 1, which measured the degree of focus on regret, we named 'intrusive thoughts of regret'; factor 2, which measured evaluation of decision-making in the past, we named 'decisional regret.'

Then, to confirm the adequacy of the scale structures, we conducted a confirmatory factor analysis with these seven items. The results

indicated that item 3 was the item with highest factor loadings for both factors 1 and 2. We then constructed two models, shown in Figure 1, and compared the fit indexes of the two models. We adopted model 2 because its fit index was higher than that of model 1.

Table 3 contains the Pearson correlation coefficients showing the correlation between the scores of regret subscales and scores for CES, overall care satisfaction, and health-related QOL. As expected, the scores for CES and overall care satisfaction negatively correlated with each regret subscale. Physical QOL and mental QOL correlated with only the intrusive thoughts subscale.

Reliability

We assessed the internal reliability of the two subscales with Cronbach's α coefficients. Internal consistency was high for both 'intrusive thoughts of regret' ($\alpha = 0.85$) and 'decisional regret' ($\alpha = 0.79$) subscales. We then defined the sums for each sub-factor as the intrusive thoughts of regret score and the decisional regret feeling score, respectively. Using these scores, we assessed test-retest reliability using correlation coefficients. Among the 71 participants who responded in both surveys, correlation coefficients among subscales were moderately high for factor 1 ($r = 0.69$, $p < 0.01$) and factor 2 ($r = 0.70$, $p < 0.01$).

Discussion

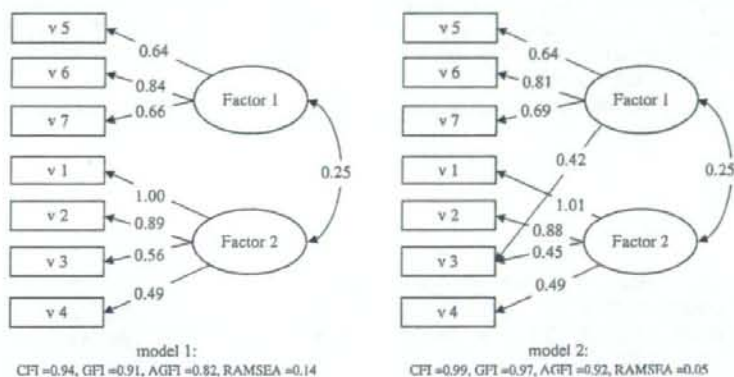
The purpose of this study was to develop a PCU's admission-related regret scale for the bereaved family and to identify its validity and reliability. Among the bereaved families, decisional-related regret was irretrievable. Furthermore, most families had thought that their past decision was fatal for the patients. By exploratory factor analysis and confirmatory factor analysis, we identified two key factors: intrusive thoughts of regret and decisional regret. This study provided good evidence of the reliability and validity of these two factors within this Japanese population. Using these two factors, we developed a new regret scale for bereaved family members, which was able to measure their intensity of regret and their self-evaluation about their decision to admit their loved ones to PCUs. Since this regret scale contains a small number of items and a simple structure, the scale is open to broad use.

We were able to delineate the structure of our two factors, intrusive thoughts of regret and decisional regret. These two factors appear to correspond to the two core components of DJT (intensity of regret and their self-evaluation) [8]: Intrusive thoughts of regret correspond to intensity of self-blame feelings, and decisional regret corre-

Table 2. Results of exploratory factor analysis

Items	Mean \pm SD	Factor loadings		Communality
		F1	F2	
Once I start thinking about possible outcomes had I made a different decision, I find it difficult to think about other matters (v6)	1.88 \pm 1.15	0.90	0.22	0.67
I had difficulty concentrating on daily activities because thoughts about regret kept entering my mind (v7)	1.72 \pm 1.10	0.83	0.18	0.62
I could not stop thinking that the situation might have changed if I had made a different decision (v5)	2.03 \pm 1.16	0.81	0.33	0.59
It was the right decision (v1*)	1.63 \pm 0.75	0.30	0.99	0.82
I would make the same decision if I had to do it again (v2*)	1.73 \pm 0.90	0.25	0.89	0.79
I regret the decision that was made (v3)	1.69 \pm 0.08	0.56	0.57	0.48
I am satisfied with the decision (v4*)	2.06 \pm 1.04	0.12	0.49	0.26

*Reversed item.

**Figure 1.** The results of confirmatory factor analysis and fit indices**Table 3.** Criterion validity as measured by Pearson correlations

Scales	CES	Overall care satisfaction	Physical QOL	Mental QOL
F1: intrusive thoughts about regret	-0.33**	-0.33**	-0.22*	-0.37**
F2: decisional regret	-0.27**	-0.46**	-0.08	-0.09

* $p < 0.05$, ** $p < 0.01$.

sponds to evaluation of decision-making and subsequent outcome. Each of the two factors contained four of the seven statements; one statement overlapped both factors. The overlapping statement, 'I regret the decision that was made', directly represented the overall regret of bereaved family members about their decision-making. Our regret scale could thereby measure three aspects of the bereaved families' regret: overall degree of regret, evaluation of decisional regret, and severity of intrusive thoughts about regret. Evaluation of the details of regret assists greatly in formulating an appropriate plan of regret management and therapy. Several recent studies have examined regret management and therapy for cancer patients [23,24]. However, to develop better evidence-based regret management or regret therapy, future research should explore the effects of

the decision-making process or options on subsequent irretrievable regrets. We believe that psychosocial theories such as reference comparisons theory or justifications theory can provide a basis for utilizing our new scale to establish effective regret management and therapy.

We found good evidence for the reliability and validity of our regret scale. Examination of the convergent validity of this scale determined that the score of CES and overall satisfaction negatively correlated with each regret subscale, indicating that this regret scale could adequately measure regrets regarding decision-making about admission to PCUs. On the other hand, both physical and mental QOL scores did not correlate with decisional regret but correlated only with intrusive thoughts of regret. This pair of findings indicates that the bereaved family's QOL is not influenced by

how much they regret their decision but rather by how often their regretful thoughts come to mind. The finding that intrusive thoughts of regret were associated with health-related QOL is in accord with the results of previous studies among adults [25]. We believe that decisional regret and intrusive thoughts of regret comprise different concepts and thus should be measured separately. Our findings suggest that intrusive thoughts of regret have the potential to affect the health-related QOL of bereaved family members.

One limitation of our study is the somewhat small sample size of our study, especially for the retest survey. We sent out retest questionnaires one month after we received a completed questionnaire. Although our study design assumed that the regret of the bereaved family did not change during this one-month period, empirical confirmation of this assumption is lacking. Our analysis of test-retest reliability yielded correlation coefficients among subscales that were moderately high.

Utilizing this new scale to assess the regret of the bereaved family should help clinicians evaluate decision-making about the admission of cancer patients into PCUs retrospectively. Use of this scale in multi-institutional outcome surveys should assist evaluation of quality differences between institutions in the decision-making process. Developing a vigilant decision-making model of cancer patients and their families and examining the association of this model with irremediable regret will require future studies in order to provide useful information about decision-making aids. Our new scale thus represents the first step for these future studies.

Acknowledgements

This research was supported by a Health and Labor Sciences Research Grant for a third term comprehensive control research for cancer.

References

- Hirai K, Miyashita M, Morita T, Sanjo M, Uchitomi Y. Good death in Japanese cancer care: a qualitative study. *J Pain Symptom Manage* 2006;31:140-147.
- Miyashita M, Sanjo M, Morita T, Hirai K, Uchitomi Y. Good death in cancer care: a nationwide quantitative study. *Ann Oncol* 2007;18:1090-1097.
- Shiozaki M, Morita T, Hirai K, Sakaguchi Y, Tsuneto S, Shima Y. Why are bereaved family members dissatisfied with specialized inpatient palliative care service? A nationwide qualitative study. *Palliat Med* 2005;19:319-327.
- Sugden R. Regret, recrimination and rationality. *Theory Decis* 1985;19:77-99.
- Kahneman D, Tversky A. The psychology preferences. *Sci Am* 1982;246:160-173.
- Gilovich T, Medvec VH. The experience of regret: what, when, and why. *Psychol Rev* 1995;102:379-395.
- Connolly T, Reb J. Regret in cancer-related decisions. *Health Psychol* 2005;24:29-34.
- Connolly T, Zeelenberg M. Regret in decision making. *Curr Dir Psychol Sci* 2002;11:212-216.
- Kaplan RM, Ganiats TG, Frosch DL. Diagnosis and treatment decisions in U.S. healthcare. *J Health Psychol* 2004;9:29-40.
- Briss P, Rimer B, Reilly B et al. Promoting informed decisions about cancer screening in communities and healthcare systems. *Am J Prev Med* 2004;26:67-80.
- Hu JC, Kwan L, Saigal CS, Litwin MS. Regret in men treated for localized prostate cancer. *J Urol* 2003;169:2279-2283.
- Clark JA, Inui TS, Silliman RA et al. Patients' perceptions of quality of life after treatment for early prostate cancer. *J Clin Oncol* 2003;21:3777-3784.
- Clark JA, Wray NP, Ashton CM. Living with treatment decisions: regrets and quality of life among men treated for metastatic prostate cancer. *J Clin Oncol* 2001;19:72-80.
- Morita T, Akechi T, Ikenaga M et al. Late referrals to specialized palliative care service in Japan. *J Clin Oncol* 2005;23:2588-2589.
- Saito S, Nomura N, Noguchi Y, Tezuka I. Translatability of family concepts into the Japanese culture: using the Family Environment Scale. *Fam Process* 1996;35:239-257.
- Voltz R, Akabayashi A, Reese C, Ohi G, Sass HM. End-of-life decisions and advance directives in palliative care: a cross-cultural survey of patients and health-care professionals. *J Pain Symptom Manage* 1998;16:153-162.
- Ruhnke GW, Wilson SR, Akamatsu T et al. Ethical decision making and patient autonomy: a comparison of physicians and patients in Japan and the United States. *Chest* 2000;118:1172-1182.
- Davison BJ, Goldenberg SL. Decisional regret and quality of life after participating in medical decision-making for early-stage prostate cancer. *BJU Int* 2003;91:14-17.
- Wrosch C, Heckhausen J. Perceived control of life regrets: good for young and bad for old adults. *Psychol Aging* 2002;17:340-350.
- 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.
- Morita T, Chihara S, Kashiwagi K. Family satisfaction with inpatient palliative care in Japan. *Palliat Med* 2002;16:185-193.
- Fukuhara S, Suzukamo Y. *Manual of the SF-8 Japanese Version*. Institute for Health Outcomes & Process Evaluation Research: Kyoto, 2004.
- Bonadonna V, Saltel P, Desseigne F et al. Cancer patients who experienced diagnostic genetic testing for cancer susceptibility: reactions and behavior after the disclosure of a positive test result. *Cancer Epidemiol Biomarkers Prev* 2002;11:97-104.
- Di Prospero LS, Seminsky M, Honeyford J et al. Psychosocial issues following a positive result of genetic testing for BRCA1 and BRCA2 mutations: findings from a focus group and a needs-assessment survey. *Can Med Assoc J* 2001;164:1005-1009.
- Wrosch C, Bauer I, Scheier MF. Regret and quality of life across the adult life span: the influence of disengagement and available future goals. *Psych Aging* 2005;20:657-670.

Original Article

Meaninglessness in Terminally Ill Cancer Patients: A Randomized Controlled Study

Tatsuya Morita, MD, Hisayuki Murata, MA, Emi Kishi, RN, Mitsunori Miyashita, RN, PhD, Takuhiro Yamaguchi, PhD, and Yosuke Uchitomi, MD, PhD

on behalf of the Japanese Spiritual Care Task Force^a

Department of Palliative and Supportive Care, Palliative Care Team, and Seirei Hospice (T.M.), Seirei Mikatahara General Hospital, Hamamatsu, Shizuoka; School of Human Culture (H.M.), Kyoto Notre Dame University, Kyoto; Palliative Care Unit (E.K.), Takatsuki Red Cross Hospital, Osaka; Department of Adult Nursing/Palliative Care Nursing (M.M.), School of Health Sciences and Nursing, and Department of Clinical Trial Data Management (T.Y.), Graduate School of Medicine, University of Tokyo, Tokyo; and Psycho-Oncology Division (Y.U.), National Cancer Center Research Institute East, Tokyo; and Psychiatry Division (Y.U.), National Cancer Center Hospital East, Kashihara City, Chiba, Japan

Abstract

Although recent empirical studies reveal that fostering patients' perception of meaning in their life is an essential task for palliative care clinicians, few studies have reported the effects of training programs for nurses specifically aimed at improving these skills. The primary aim of this randomized controlled trial was to determine the effects of an educational workshop focusing on patients' feelings of meaninglessness on nurses' confidence, self-reported practice, and attitudes toward caring for such patients, in addition to burnout and meaning of life. The study was designed as a single-institution, randomized controlled trial using a waiting list control. The intervention consisted of eight 180-minute training sessions over four months, including lectures and exercises using structured assessment. A total of 41 nurses were randomly allocated to three groups, which were separately trained, and all were evaluated four times at three-month intervals (before intervention, between each intervention, and after the last intervention). Assessments included validated Confidence and Self-Reported Practice scales, the Attitudes Toward Caring for Patients Feeling Meaningless Scale (including willingness to help, positive appraisal, and helplessness items), the Maslach Burnout Scale, job satisfaction, and the Functional Assessment of Chronic Illness Therapy-Spiritual (FACIT-Sp). One participant withdrew from the study before the baseline evaluation, and the remaining 40 nurses completed the study. The nurses were all female and had a mean age of 31 ± 6.4 , and mean clinical experience of 8.9 ± 5.5 years. There were no significant differences in background among the groups. The intervention effects were statistically significant on the Confidence Scale, the Self-Reported Practice Scale, and the

Address correspondence to: Tatsuya Morita, MD, Department of Palliative and Supportive Care, Palliative Care Team, and Seirei Hospice, Seirei Mikatahara General Hospital, 3453 Mikatahara-cho, Hamamatsu, Shizuoka 433-8558, Japan. E-mail: tmorita@sis.seirei.or.jp

^aSee Appendix for list of members.

Accepted for publication: April 6, 2008.

willingness to help, positive appraisal, and helplessness subscales, in addition to the overall levels of burnout, emotional exhaustion, personal accomplishment, job satisfaction, and the FACIT-Sp. The change ratio of each parameter ranged from 5.6% (willingness to help) to 37% for the helplessness score and 51% on the Confidence Scale. The percentages of nurses who evaluated this program as "useful" or "very useful" were 85% (to understand the conceptual framework in caring for terminally ill patients with meaninglessness), 80% (to foster nurses' personal values), and 88% (to know how to provide care for patients with meaninglessness). This educational intervention had a significant beneficial effect on nurse-perceived confidence, practice, and attitudes in providing care for patients feeling meaninglessness, in addition to the levels of burnout and spiritual well being of nurses. *J Pain Symptom Manage* 2008;■■■■. © 2008 U.S. Cancer Pain Relief Committee. Published by Elsevier Inc. All rights reserved.

Key Words

Palliative care, neoplasms, education, spiritual care, suffering, meaning, nurse

Introduction

Recent empirical studies reveal that fostering patients' perception of meaning in their life is an essential task for palliative care clinicians.¹⁻⁴ In Japan, multiple surveys have identified that terminally ill cancer patients experience considerable levels of meaninglessness.^{5,6} Our group recently proposed a conceptual framework for psycho-existential care for Japanese patients.⁷ We defined psycho-existential suffering as pain caused by extinction of the being and the meaning of the self. We assumed that psycho-existential suffering is caused by the loss of essential components of meaning for human beings: loss of relationships with others, loss of autonomy, and loss of future (temporality). In this model, sense of meaning is interpreted as a main outcome, as consistent with some psychometric instruments measuring sense of meaning as a core concept of the state of spiritual well being.⁷

In fostering a sense of meaning in terminally ill cancer patients, nurses play a major role. Nurses often experience difficulty and emotional stress when facing terminally ill cancer patients with unrelieved suffering.⁸⁻¹⁰ One of the sources of nurses' stress is the lack of an adequate training system to improve the skills required to care for such patients.⁸⁻¹⁰ General training in communication skills has been described and evaluated.^{11,12} A few studies also have reported the effects of training programs for nurses, specifically aimed at improving skills to relieve meaninglessness in terminally

ill cancer patients.¹³⁻¹⁶ These pioneer studies have major limitations, however, including no control groups, a nonstructured intervention, and the use of nonvalidated measurement tools.

In our previous work,¹⁷ we validated measurement tools to quantify nurses' self-reported practice and attitudes toward caring for terminally ill cancer patients feeling meaninglessness, and explored the effects of a five-hour educational workshop focusing on meaninglessness on nurses' self-reported practice, attitudes toward caring for such patients, confidence, burnout, death anxiety, and meaning of life. After the short-term educational session, the nurses' self-reported practice and confidence significantly improved, and helplessness, emotional exhaustion, and death anxiety significantly decreased. The percentage of nurses who evaluated this program as "useful" or "very useful" was about 80%. This result suggested that the five-hour workshop has a beneficial effect on nurse-reported practice, attitudes, and confidence in providing care for terminally ill cancer patients feeling meaninglessness. Lack of control group in the pilot study, however, limited the determination of the effects of the intervention as compared with conventional care.

The primary aim of this randomized controlled trial was thus to determine the effects of an educational workshop focusing on patient meaninglessness on nurses' confidence, self-reported practice, and attitudes toward

caring for such patients, in addition to nurses' burnout and meaning of life.

Methods

This study was designed as a randomized controlled trial using a waiting list control (Fig. 1). The nurses were recruited from a single general hospital. A total of 41 nurses were randomly allocated to three groups using the envelope method. One participant (Group 3) withdrew from the study before the baseline evaluation, but we tried no supplementary recruitment because of adequate sample size. The remaining 40 nurses completed the study. We evaluated the nurses four times at three-month intervals (before intervention, between each intervention, and after the last intervention).

The Institutional Review Board approved the scientific and ethical validity of this study, and the nurses gave written consent.

Subjects

The nurses were all female and had a mean age of 31 ± 6.4 years (median, 29; range, 21–47), and mean clinical experience of

8.9 ± 5.5 years (median, 8.0; range, 1 to 22). Eleven nurses worked in the palliative care unit. All nurses were general practice nurses, including those working in palliative care units (none of the nurses had formal certification in palliative care, such as clinical nurse specialists). There were no significant differences in the participants' backgrounds among the groups (Table 1).

Interventions

The workshop was principally based on Murata and Morita's conceptual framework, and specifically focused on the care of terminally ill cancer patients feeling meaninglessness.⁷ The intervention was the same throughout the study periods. The second author (H. M.) provided all lectures.

The workshop consisted of eight sessions over four months, and each session took 180 minutes. Table 2 summarizes the program contents. In the first three introductory sessions, participants were educated about basic communication skills through lectures and exercises. In the exercise section, each participant was requested to report short, typically 20 to 30 sentences, verbatim records of their actual

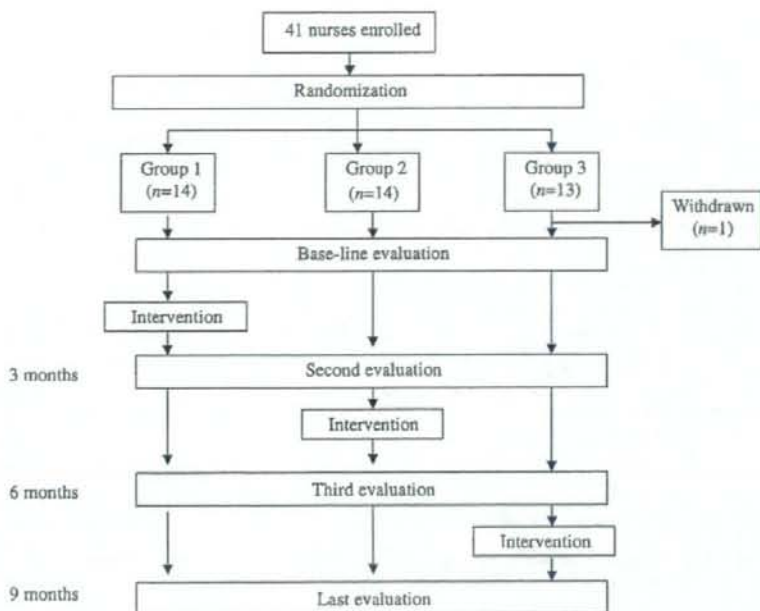


Fig. 1. Study protocol.

Table 1
Participants' Backgrounds

	Group 1	Group 2	Group 3	P
	(n = 14)	(n = 14)	(n = 13)	
Age, years (mean ± SD)	31 ± 5.2	32 ± 8.5	31 ± 5.3	0.94
Clinical experience, years (mean ± SD)	8.1 ± 3.7	9.8 ± 7.1	8.6 ± 5.3	0.73
Working in the palliative care unit, n (%)	3 (21)	4 (29)	4 (31)	0.77

experiences in their routine practice, and received face-to-face feedback based on group discussion about appropriate listening skills.

In the following two sessions, participants were educated about the conceptual framework of meaningfulness used in this practice, and how to use the Spiritual Conference Summary Sheet. In the last three sessions, participants were requested to complete the Spiritual Conference Summary Sheet for actual patients: to identify which of the patient's statements are expressions of meaningfulness from the verbatim record as the origin of the patient's meaningfulness (temporality, relationships, or autonomy), and to establish a care plan to alleviate the patient's sense of

Table 2
Program Contents

Session	Contents
1	Lecture (overview and what is "helping others?") (90 minutes) Exercise: read and discuss three verbatim case records (90 minutes)
2	Lecture (sympathy and active listening) (90 minutes) Exercise: read and discuss three verbatim case records (90 minutes)
3	Lecture (communication) (90 minutes) Exercise: read and discuss three verbatim case records (90 minutes)
4	Lecture (conceptual framework of meaningfulness) (90 minutes) Exercise: read and discuss three verbatim case records (90 minutes)
5	Lecture (how to use the Spiritual Conference Summary Sheet) (90 minutes) Exercise: read and discuss three verbatim case records (90 minutes)
6	Exercise: case discussion based on four Spiritual Conference Summary Sheets (180 minutes)
7	Exercise: case discussion based on four Spiritual Conference Summary Sheets (180 minutes)
8	Exercise: case discussion based on four Spiritual Conference Summary Sheets (180 minutes)

meaninglessness in daily nursing practice by strengthening the factors supporting meaning and alleviating the factors causing meaningfulness. In these sessions, four Spiritual Conference Summary Sheets were discussed under supervision from the second author, and all participants received additional individual, written feedback.

Assessment and care planning based on the Spiritual Conference Summary Sheet is an essential part of this intervention. The Spiritual Conference Summary Sheet (Fig. 2) was designed to respectively assess the source of meaning for each patient (i.e., temporality, relationships, or autonomy) from patients' actual dialogue.

Measurement Instruments

We adopted the Confidence and Self-Reported Practice scales, and the Attitudes toward Caring for Patients Feeling Meaningless Scale (willingness to help, positive appraisal, and helplessness) as primary end points for this study. The rationale and scale development process were described in detail in our previous article.¹⁷ In addition, we measured the levels of burnout (Maslach Burnout Scale^{18,19}) and the nurses' own spiritual well being (Functional Assessment of Chronic Illness Therapy-Spiritual [FACIT-SP]^{20,21}) as secondary end points.

Confidence. Confidence in caring for terminally ill cancer patients with meaningfulness was evaluated on a single Likert-type scale from 1: "not confident at all" to 7: "very confident" for the question "With what degree of confidence can you communicate with terminally ill cancer patients saying, 'I can see no meaning in life?'"¹⁷

Self-Reported Practice Scale. The Self-Reported Practice Scale quantifies the level of self-reported adherence to recommended clinical practice in helping terminally ill patients to find meaning in their lives.¹⁷ Self-reported practice was evaluated by the level of adherence to six recommended practice statements on a Likert-type scale from 1: "not do at all" to 5: "always": "I try to know what make the patient's life meaningful," "I try to know what strengthens or weakens the meaning of life for the patient," "I try to know how the

Dimension	Patient dialog	Assessment	Care plan
Relationships	P4(underlined) P5(underlined)	Mr. A reflected on his past and gave a positive meaning to his bitter experience, whereby his feelings changed from repentance to gratefulness and reconciliation. Mr. A felt supported by someone listening to him.	Listen to Mr. A's reflections on his life and encourage him to talk to strengthen the meaning from his relationships with family and relatives. Continue to listen attentively to maintain a relationship with others.
Temporality	"I'm finished. There is no sense in living."	Mr. A sensed the ineffectiveness of treatment and felt that there was no hope of cure. This caused him to feel that he had no future and that his life was meaningless from temporality.	Encourage him to reflect on his past life, to regain the meaning supported by his past and relationships, not by the future.
Autonomy		He stays in bed all day due to paralysis of the bilateral lower limbs and dependence causes meaningless from autonomy.	Encourage reflections on life to divert their patients' value from dependency to the meaningful past.
Assessment and Planning		Mr. A feels his treatment to be ineffective and suffers from feelings of having no future, and physical dependence. No future and dependence causes meaningless from temporality and autonomy. However, he could reflect on his past of meaningful relationships. The care plan therefore would be to continue listening carefully to his reflections on life to increase the meaningfulness of his past experiences and relationships, rather than the future and physical autonomy.	

Verbatim record N: nurse P: patient

N1: How are you, Mr. A?

P1: ... at night. I get up in the middle of the night, and I can't help thinking of one thing after another.

N2: You think of many things?

P2: Yeah. (After being silent for a while) You visit other patients and listen to them, too?

N3: Yes, there are others, too.

P3: I guess it's pretty hard for a mother with small children. (Silent for a while)...

N4: (Waiting)

P4: I lost my mother, too, when I was 6. She was 36. Then, I was taken care of by a stepmother, but it was difficult to get used to her. We were never on good terms. (Weeps) I was raised by 3 mothers: My own mother, nurse, and stepmother. But, when my father died, I said at his funeral, "I was brought up by 3 mothers, and this was my greatest fortune," showing my thanks to relatives. That was good, because everyone thanked me for saying it. (Weeps)

N5: At your father's funeral, you said you were very lucky to have been brought up by 3 mothers and thanked your relatives? And you felt good, because it made everybody grateful?

P5: Yes. (Weeps) (Looking straight at me) I thank you for coming today. I really do. You are coming again to listen to me? It makes me feel relieved.

N6: Yes, I am. I am looking forward to listening to you again. (Leaves the room)

Fig. 2. Spiritual conference summary sheet.

patient's life is supported," "I try to know what meaning the disease has for the patient," "I try to understand the patient's wishes," and "I try to know what is important to the patient." We defined the scale score as the mean of the total score of the responses, and thus the score ranged from 1 to 5, with a higher score indicating a higher level of performance of recommended practices. Reliability was high, and convergent validity was examined by moderate correlation with self-reported practice about general communication.¹⁷

Attitudes Toward Caring for Patients Feeling Meaningless: Willingness to Help, Positive Appraisal, and Helplessness. Willingness to help, positive appraisal, and helplessness quantify the degree of willingness to make an effort to help patients feeling meaninglessness, nurses' positive appraisal of their experience of encountering patients feeling meaninglessness, and nurses' perception of helplessness when facing patients feeling meaninglessness, respectively. These were evaluated by levels of agreement with several statements on a Likert-type scale from 1: "never" to 7: "very much." The instructions specifically presented a situation in which the nurse faced a terminally ill cancer patient suffering from meaninglessness. The item questions were: "I feel willing to do something to relieve the patient's suffering," "I think how I can support the patient effectively," and "I wish to relieve the patient's suffering as much as possible" (willingness to help; three items, range = 1-3); "I feel grateful that the patient has told me," and "I feel that the patient trusts me" (positive appraisal; two items, range = 1-3); "I feel helplessness," "I feel like escaping," and "I feel willing to be involved (reversed item)" (helplessness; three items, range = 1-3), respectively. Higher scores indicated higher levels of nurses' willingness to help, positive appraisal of their experience, and perception of helplessness, respectively. Reliability was high, construct validity was confirmed using confirmatory factor analysis, and convergent validity was examined by moderate correlation with the Frommelt Scale.^{17,22,23}

Burnout. Professional burnout was measured using the Maslach Burnout Inventory,^{18,19} which measures three components of burnout syndrome: emotional exhaustion, depersonalization,

and lack of personal accomplishment, in addition to overall levels of burnout (visual analog scale, range = 0-100).¹⁸ The psychometric properties of the Japanese version have been confirmed.¹⁹ In addition, job satisfaction was measured on a 0-10 rating scale following the previous study.¹⁴

Spiritual Well Being. Nurses' own spiritual well being was measured using the FACIT-SP.^{20,21} The psychometric property of the Japanese version has been confirmed.²¹

Overall Evaluation. Finally, we asked the respondents to rate their overall evaluation about the usefulness of this program in terms of: 1) understanding the conceptual framework in caring for terminally ill patients feeling meaninglessness; 2) helping in self-disclosing nurses' personal beliefs, values, and life goals; and 3) helping in learning how to provide care for patients feeling meaninglessness in clinical practice.¹⁷ We used the second question, given the possibility that nurses' own spirituality might change through this educational session about patient suffering,¹⁷ although the intervention itself did not deal with nurses' own spirituality. The choices were "not useful," "slightly not useful," "slightly useful," "useful," and "very useful."

Statistical Analysis

We first compared participants' backgrounds (age, clinical experience, and working setting) among groups by analysis of variance or Chi-square test, as appropriate. We then calculated the change ratio of each score from the mean value of each score at the baseline and just after intervention for all end points. Finally, we tested the statistical significance of treatment effect using the mixed effect model for all end points. In all analyses, the significance level was set at $P < 0.05$ and a two-sided test was used. All analyses were conducted using statistical package SAS (SAS Institute, Cary, NC).

Results

Primary End Points

As shown in Fig. 3, the intervention effects were statistically significant for all primary end points: Confidence and Self-Reported Practice scales, and Attitudes toward Caring for Patients

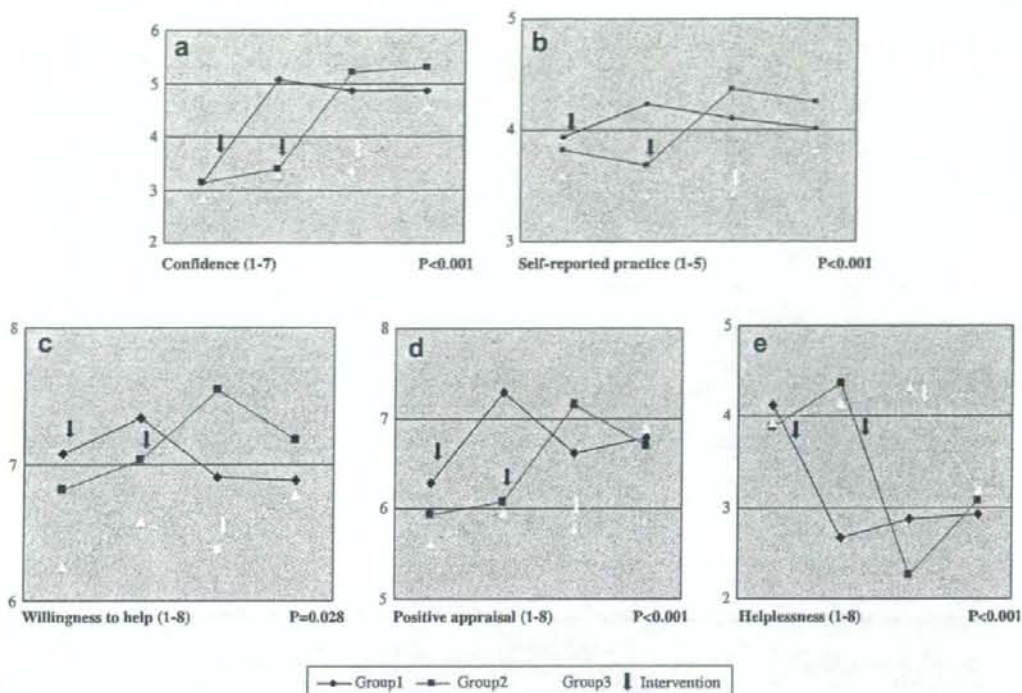


Fig. 3. Primary end points.

Feeling Meaningless (willingness to help, positive appraisal, and helplessness). The changes in these primary end points were: 5.6% (willingness to help), 12% (self-reported practice), 18% (positive appraisal), 37% (helplessness), and 51% (Confidence Scale) (Table 3).

Secondary End Points

As shown in Fig. 4, the intervention effects were statistically significant for the overall levels of burnout, emotional exhaustion, personal accomplishment, job satisfaction, and nurses' own spiritual well being. The changes in these parameters were: 12% (emotional exhaustion), 13% (personal accomplishment), 15% (depersonalization), 21% (overall burnout, job satisfaction), and 23% (spiritual well being) (Table 3).

Overall Evaluation

The percentages of nurses who evaluated this program as "useful" or "very useful" were 85% (to understand the conceptual framework in caring for terminally ill patients feeling meaninglessness), 80% (to help in self-discussing nurses' personal beliefs, values, and life goals),

and 88% (to help in learning how to provide care for patients feeling meaninglessness).

Discussion

The most important finding of this study is a significant and clear beneficial effect of an educational intervention focusing on patient

Table 3
Changes in Primary and Secondary End Points

	Before	After	Change (%)
Confidence (1-7)	3.29	4.97	51
Self-Reported Practice score (1-5)	3.70	4.16	12
Attitudes toward caring for patients feeling meaningless			
Willingness to help (1-8)	6.85	7.24	5.6
Positive appraisal (1-8)	6.06	7.12	18
Helplessness (1-8)	4.27	2.68	-37
Maslach Burnout Inventory			
Overall burnout (0-100)	66.1	52.1	-21
Emotional exhaustion (1-7)	4.11	3.62	-12
Personal accomplishment (1-7)	4.16	4.70	13
Depersonalization (1-7)	1.96	1.67	-15
Job satisfaction (0-10)	5.65	6.84	21
Spiritual well being (FACIT-Sp, 0-4)	2.15	2.65	23

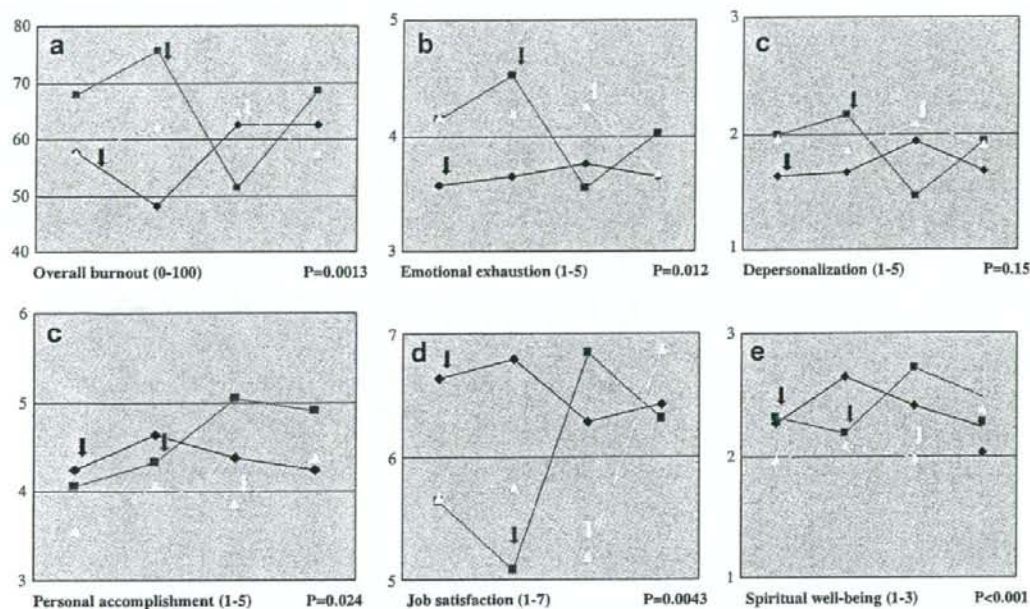


Fig. 4. Secondary end points.

meaninglessness on nurses' confidence, nurse-reported practice, and attitudes in providing care for such patients. This finding confirms our preliminary study that the intervention could provide considerable benefits for confidence, nurse-reported practice, and attitudes. Of note was the great change in nurses' confidence (51%) and helplessness (37%), in addition to the high evaluation of the overall usefulness of the workshop in learning how to provide care in clinical practice compared with a previous study (80% vs. 34%).¹⁵ This result strongly suggests that this educational program can provide nurses with clinically useful specific strategies for caring for patients feeling meaninglessness.

From the fact that the change rate of willingness to help was much smaller than other variables, it could be interpreted that the participating nurses had voluntarily participated in this program and had higher motivation to help such patients. As for nurse-reported burnout, job satisfaction, and spiritual well being, our preliminary study failed to demonstrate beneficial effects,¹⁷ but the present study, in addition to Wasner et al.'s pioneer work, showed positive results.¹⁴ This discrepancy could be explained by the intensity of

the intervention: our preliminary work was only a five-hour workshop, whereas the two positive studies consisted of at least three month continuing education. The greater difference in the scores in the present study vs. Wasner et al.'s study could indicate that our intervention has a stronger role in preventing nurses' burnout: 21% vs. 6.6% (overall burnout), 21% vs. 9.7% (job satisfaction), and 23% vs. 7.8% (spiritual well being on the FACIT-Sp) 14. From the fact that intervention effects on burnout items in Group 1 was relatively lower compared with Groups 2 and 3, it could be interpreted that the instructor became more skillful in preventing nurses' burnout through the study periods.

A concern about this intervention is the possibility that the intervention effect may not be maintained, because some variables returned to the baseline levels after six to nine months. The finding suggests that this intervention may require periodic exposure or "maintenance therapy," and this should be a main focus of future research.

This study has several limitations. First, as this study measured nurse-reported outcomes, a future study should examine patient outcomes and/or observer-rating behavior of nurses.