

Table 5 Determinants of choosing home as preferred place of care

	With pain			Dependent without pain				
	Univariate analyses			Univariate analyses				
	Home (n=1,931)	Other than home (n=1,742)	P	Home (n=1,416)	Other than home (n=2,249)	P	Multivariate analysis ^a	Multivariate analysis ^b
Age	58±10	61±10	<0.001	60±11	60±10	0.58	0.98 [0.97–0.98]	1.3 [1.1–1.5]
Gender (male)	46% (n=884)	44% (n=760)	0.19	49% (n=691)	43% (n=962)	<0.001		
Experience that one of the family members had cancer	46% (n=880)	44% (n=761)	0.25	46% (n=655)	44% (n=993)	0.21		
Concerns								
Unable to achieve adequate pain relief	3.25±0.81	3.33±0.85	0.006	3.26±0.83	3.31±0.84	0.083		
Unable to adequately respond to sudden changes in out-of-hours	3.79±0.90	3.88±0.89	0.001	3.77±0.92	3.87±0.88	0.001	0.91 [0.84–0.99]	0.92 [0.85–1.0]
Family physician visiting home is unavailable	3.56±1.03	3.57±1.05	0.93	3.53±1.05	3.58±1.04	0.15		
Family burden is heavy	4.14±0.80	4.23±0.81	0.001	4.10±0.84	4.22±0.79	<0.001	0.88 [0.80–0.97]	0.87 [0.79–0.95]
Too expensive	3.63±0.97	3.71±1.00	0.015	3.63±0.99	3.69±0.98	0.070		

C.I. confidence intervals, values are the means of agreement for each statement from 1 (disagree) to 5 (strongly agree)

^a $R^2 = 0.027$

^b $R^2 = 0.013$

unexpected given that the Japanese health care system is of a similar standard and scope throughout the country. The fact that four areas with quite different characteristics in terms of urban–rural areas and existing palliative care systems produced essentially the same results suggests that preference regarding place of care and place of death would be similar among the general population throughout Japan.

The second important finding of this study was the clarification of preferred place of care and place of death for cancer patients as a representative sample of each community. The place of care and place of death preferences of cancer patients surveyed in this study were basically similar to those of the general public, although fewer cancer patients chose home–home and more chose hospital–hospital compared to the general public. These findings are consistent with previous similar studies [6, 11], although recent studies also indicated that preference about preferred place of care and place of death is not a steady concept and can change over time through discussions between health care professionals and patients [18, 19]. Our findings therefore indicate that preference surveying among the general population could provide an alternative to patient surveying as a representative sample of the community as a whole. However, patient surveys on homogeneous samples of a certain clinical stage and/or qualitative longitudinal studies are still needed in the future to more accurately estimate preferences in cancer patients and to obtain deeper insights about preferred place of care and place of death. In the meantime, establishing more accessible and higher quality home care and hospice service is of great importance given the finding that almost half of our surveyed cancer patients preferred home as place of care and a considerable number of cancer patients preferred hospice [20].

This study also revealed a high level of concern among the general public and cancer patients about dying at home, and that this concern significantly affected the preferred place of care and place of death. The concerns most commonly reported across all respondents included family burden (80%), being unable to adequately respond to sudden changes in out-of-hours care (70%), availability of family physicians visiting home (60%), and expense (50%). These figures are again very close to the data provided by the Ministry of Health, Labor, and Welfare that the most common difficulties with home care surround concerns about the burden to family and sudden changes in physical conditions [8]. Our results also correspond to the previous finding that significant determinants of actual home death include the levels of caregiving at home, such as living with relatives, expanded family support, and caregiver's preference [9]. A small number of studies also identified predictors of patient preference for home as place of care or place of death to be lower levels of concern about being a burden to family and availability of informal caregiver, in addition to younger

age, male, better physical health, family physician visiting home available, and the concept of a good death [6, 7, 11–14]. The findings of this study is also generally consistent with previous studies from Western countries, and confirmed that many among the general public and patient population have similar concerns about home care and that this significantly contributes to the expressed preference [11–14].

Family burden in this context includes patient-perceived burden and actual family burden in caregiving. Multiple studies indicate that patient-perceived burden is one of the most serious stressors in terminally ill cancer patients, even if family members do not report actual caregiving burden [21, 22]. Other studies confirmed that perceived burden is a major component in a cancer patient's decision regarding home care [23, 24]. On the other hand, family may experience actual burden from caregiving at home regardless of the levels of patient-perceived burden, especially in caring patients with low functional status [25, 26]. In addition, meta-analyses identified inadequate information including emergency measures and out-of-hour support as unmet needs of informal caregivers [27, 28], and that educational intervention alone achieves minimum beneficial effects on the concerns of family burden and being unable to adequately respond to sudden changes out-of-hours. These findings suggested that clinicians should alleviate such concerns through ongoing continual support in how to address problems at home, arranging regional resources to reduce actual family burden, and the provision of psychological support for patient-perceived burden [27–30].

This study had several limitations. The response rate of 50% was not particularly high, and thus the findings are not easily applicable. We believe, however, that this is an acceptable limitation because other population-based surveys conducted by the Ministry of Health, Labor, and Welfare obtained similar results [8]. Furthermore, as we could not include some areas with local culture, e.g., Okinawa and islands areas, the results might be applied for these areas. We believe, however, the overall conclusion is less likely to change because major typical areas in Japan were surveyed in this study and the 2008 national surveys.

In conclusion, there was minimum difference in preferred place of care and place of death among the general public across four regions; cancer patients were less likely to report home as preferred place of care than the general public, and among the cancer patients at least 40% preferred home as the place of care and a considerable number preferred hospice. The major concerns significantly associated with preferred place of care were concern about family burden and being unable to adequately respond to sudden changes out-of-hours. Home care and hospice service in Japan needs to be more accessible and of good quality. In addition, clinicians should alleviate patient concerns about burden to their

family and being unable to adequately respond to sudden changes out-of-hours by ongoing continual support regarding home problems, arranging regional resources to reduce actual family burden, and providing psychological support for patient-perceived burden.

References

- Steinhauser KE, Christakis NA, Clipp EC, McNeilly M, McIntyre L, Tulsky JA (2000) Factors considered important at the end of life by patients, family, physicians, and other care providers. *JAMA* 284:2476–2482
- Miyashita M, Sanjo M, Morita T, Hirai K, Uchitomi Y (2007) Good death in cancer care: a nationwide quantitative study. *Ann Oncol* 18:1090–1097
- Detering KM, Hancock AD, Reade MC, Silvester W (2010) The impact of advance care planning on end of life care in elderly patients: randomized controlled trial. *BMJ* 340:c1345
- Wood J, Storey L, Clark D (2007) Preferred place of care: an analysis of the 'first 100' patient assessments. *Palliat Med* 21:449–450
- Meeussen K, Van de Block L, Bossuyt N et al (2009) GPs' awareness of patients' preference for place of death. *Br J Gen Pract* 59:665–670
- Higginson IJ, Sen-Gupta GJ (2000) Place of care in advanced cancer: a qualitative systematic literature review of patient preferences. *J Palliat Med* 3:287–300
- Sanjo M, Miyashita M, Morita T et al (2007) Preferences regarding end-of-life cancer care and associations with good-death concepts: a population-based survey in Japan. *Ann Oncol* 18:1539–1547
- Ministry of Health, Labor, and Welfare. Available at <http://www.mhlw.go.jp/shingi/2004/07/s0723-8d8.html>. (In Japanese)
- Gomes B, Higginson IJ (2006) Factors influencing death at home in terminally ill patients with cancer: systematic review. *BMJ* 332:515–521
- Fukui S, Fukui N, Kawagoe H (2004) Predictors of place of death for Japanese patients with advanced-stage malignant disease in home care settings: a nationwide survey. *Cancer* 101:421–429
- Foreman LM, Hunt RW, Luke CG, Roder DM (2006) Factors predictive of preferred place of death in the general population of South Australia. *Palliat Med* 20:447–453
- Choi KS, Chae YM, Lee CG et al (2005) Factors influencing preferences for place of terminal care and of death among cancer patients and their families in Korea. *Support Care Cancer* 13:565–572
- Brazil K, Howell D, Bedard M, Krueger P, Heidebrecht C (2005) Preferences for place of care and place of death among informal caregivers of the terminally ill. *Palliat Med* 19:492–499
- Yamasaki M, Ebihara S, Freeman S et al (2008) Sex differences in the preference for place of death in community-dwelling elderly people in Japan. *J Am Geriatr Soc* 56:376
- Morita T, Akechi T, Ikenaga M et al (2005) Late referrals to specialized palliative care service in Japan. *J Clin Oncol* 23:2637–2644
- Yamagishi A, Morita T, Miyashita M et al (2008) 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. *Am J Hosp Palliat Care* 25:412–418
- Agar M, Currow DC, Shelby-James TM, Plummer J, Sanderson C, Abernethy AP (2008) Preference for place of care and place of death in palliative care: are these different questions? *Palliat Med* 22:787–795

18. Munday D, Petrova M, Dale J (2009) Exploring preferences for place of death with terminally ill patients: qualitative study of experiences of general practitioners and community nurses in England. *BMJ* 338:b2391
19. Butow PN, Maclean M, Dunn SM, Tattersall MHN, Boyer MJ (1997) The dynamics of change: cancer patients' preferences for information, involvement and support. *Ann Oncol* 8:857–863
20. Thomas C, Morris SM, Clark D (2004) Place of death: preferences among cancer patients and their carers. *Soc Sci Med* 58:2431–2444
21. McPherson CJ, Wilson KG, Murray MA (2007) Feeling like a burden: exploring the perspectives of patients at the end of life. *Soc Sci Med* 64:417–427
22. Akazawa T, Akechi T, Morita T et al (2010) Self-perceived burden in terminally ill cancer patients: a categorization of care strategies based on bereaved family members' perspectives. *J Pain Symptom Manage* 40(2):224–234
23. Tang ST (2003) When death is imminent: where terminally ill patients with cancer prefer to die and why. *Cancer Nurs* 26:245–251
24. Gott M, Seymour J, Bellamy G, Clark D, Ahmedzai S (2004) Older people's views about home as a place of care at the end of life. *Palliat Med* 18:460–467
25. Grunfeld E, Coyle D, Whelan T et al (2004) Family caregiver burden: results of a longitudinal study of breast cancer patients and their principal caregivers. *CMAJ* 170:1795–1801
26. Shaw C, McNamara R, Abrams K et al (2009) Systematic review of respite care in the frail elderly. *Health Technol Assess* 13:1–224, iii
27. Bee PE, Barnes P, Luker KA (2008) A systematic review of informal caregivers' needs in providing home-based end-of-life care to people with cancer. *J Clin Nurs* 18:1379–1393
28. Docherty A, Owens A, Asadi-Lari M, Petchey R, Jacky W, Carter YH (2008) Knowledge and information needs of informal caregivers in palliative care: a qualitative systematic review. *Palliat Med* 22:153–171
29. Harding R, Higginson IJ (2003) What is the best way to help caregivers in cancer and palliative care? A systematic literature review of interventions and their effectiveness. *Palliat Med* 17:63–74
30. Sato K, Miyashita M, Morita T, Suzuki M (2009) The long-term effect of a population-based educational intervention focusing on end-of-life home care, life-prolongation treatment, and knowledge about palliative care. *J Palliat Care* 25:206–212

STUDY PROTOCOL

Open Access

A region-based palliative care intervention trial using the mixed-method approach: Japan OPTIM study

Tatsuya Morita^{1*}, Mitsunori Miyashita², Akemi Yamagishi³, Nobuya Akizuki⁴, Yoshiyuki Kizawa⁵, Yutaka Shirahige⁶, Miki Akiyama⁷, Kei Hirai⁸, Motohiro Matoba⁹, Masako Yamada¹⁰, Taketoshi Matsumoto¹¹, Takuhiro Yamaguchi¹² and Kenji Eguchi¹³

Abstract

Background: Disseminating palliative care is a critical task throughout the world. Several outcome studies explored the effects of regional palliative care programs on a variety of end-points, and some qualitative studies investigated the process of developing community palliative care networks. These studies provide important insights into the potential benefits of regional palliative care programs, but the clinical implications are still limited, because: 1) many interventions included fundamental changes in the structure of the health care system, and, thus, the results would not be applicable for many regions where structural changes are difficult or unfeasible; 2) patient-oriented outcomes were not measured or explored only in a small number of populations, and interpretation of the results from a patient's view is difficult; and 3) no studies adopted a mixed-method approach using both quantitative and qualitative methodologies to interpret the complex phenomenon from multidimensional perspectives.

Methods/designs: This is a mixed-method regional intervention trial, consisting of a pre-post outcome study and qualitative process studies. The primary aim of the pre-post outcome study is to evaluate the change in the number of home deaths, use of specialized palliative care services, patient-reported quality of palliative care, and family-reported quality of palliative care after regional palliative care intervention. The secondary aim is to explore the changes in a variety of outcomes, including patients' quality of life, pain intensity, family care burden, and physicians' and nurses' knowledge, difficulties, and self-perceived practice. Outcome measurements used in this study include the Care Evaluation Scale, Good Death Inventory, Brief pain Inventory, Caregiving Consequence Inventory, Sense of Security Scale, Palliative Care Knowledge test, Palliative Care Difficulties Scale, and Palliative Care Self-reported Practice Scale. Study populations are a nearly representative sample of advanced cancer patients, bereaved family members, physicians, and nurses in the region.

Qualitative process studies consist of 3 studies with each aim: 1) to describe the process in developing regional palliative care in each local context, 2) to understand how and why the regional palliative care program led to changes in the region and to propose a model for shaping regional palliative care, and 3) to systematically collect the barriers of palliative care at a regional level and potential resolutions. The study methodology is a case descriptive study, a grounded theory approach based on interviews, and a content analysis based on systemically collected data, respectively.

Discussion: This study is, to our knowledge, one of the most comprehensive evaluations of a region-based palliative care intervention program. This study has 3 unique aspects: 1) it measures a wide range of outcomes, including quality of care and quality of life measures specifically designed for palliative care populations, whether patients died where they actually preferred, the changes in physicians and nurses at a regional level; 2) adopts

* Correspondence: tmorita@sis.seirei.or.jp

¹Department of Palliative and Supportive Care, Palliative Care Team, and Seirei Hospice, Seirei Mikatahara, General Hospital 3453 Mikatahara-cho, Hamamatsu, Shizuoka 433-8558, Japan

Full list of author information is available at the end of the article

qualitative studies along with quantitative evaluations; and 3) the intervention is without a fundamental change in health care systems. A comprehensive understanding of the findings in this study will contribute to a deeper insight into how to develop community palliative care.

Trial Registration: UMIN Clinical Trials Registry (UMIN-CTR), Japan, UMIN000001274.

Background

Palliative care is an essential part of integrated cancer treatment [1]. Palliative care should be provided throughout an entire region, and several outcome studies have explored the effects of regional palliative care programs on places of death, the use of palliative care resources, patient-reported outcomes, family-reported outcomes, and cost [2-9]. In a cluster randomized controlled trial, a regional palliative care intervention, including developing a specialized inpatient palliative care service at an academic hospital, strengthening the cooperation between specialized palliative care and community health care services, developing clinical guidelines, and educational programs for community health care providers, contributed to an increase in the number of home deaths and higher levels of family satisfaction, but the patient-reported quality of life, measured by the EORTC-C30, was not significantly different [2-4]. A pioneer work as a regional palliative care model, the Edmonton program, observed that constructing a novel regional system, including a regional palliative care office to coordinate palliative care activities at specialist and community levels throughout the region, resulted in an increased number of home deaths and use of specialized palliative care services [5,6]. A recent palliative care quality improvement project in Ontario included developing and disseminating standard clinical tools for collaborative care planning and symptom assessment [7,8]. The audit study from this project demonstrated an increased documentation of symptoms and decreased use of emergency visits, while the symptom intensity and family satisfaction did not significantly improve. In addition, the Catalonia WHO demonstration project demonstrated an increase in the quantity and variety of specialized palliative care services and potential cost-saving effects [9]. More recently, the U.K. implemented the Gold Standards Framework, stressing communication and coordination in the community through developing a palliative care patient registry and regular meetings [10-13]. Qualitative studies suggest the most important benefit of the Gold Standards Framework is facilitating communication among health care professionals in the community, although the direct effects on patient and/or family outcomes were formally unmeasured. Multiple studies from Canada, the Netherlands, and Australia which investigated the process of developing community palliative care networks again revealed the perceived

importance of an increase in personal and formal contacts in health care professionals [14-16].

These studies provide important insights into the potential benefits of regional palliative care programs, but the clinical implications are still limited, because: 1) the interventions included a fundamental change in the structure of the health care system (Norway, Edmonton, Catalonia, and the U.K.), and, thus, the results would not be applicable for many regions where structural changes are difficult or unfeasible; 2) patient-oriented outcomes were not measured or explored only in a small number of populations, and interpretation of the results from a patient's view is difficult; and 3) no studies adopted the mixed-method approach using both quantitative and qualitative methodologies to interpret the complex phenomenon from multidimensional perspectives [17-20].

We believe, therefore, that a new study should include: 1) an intervention program available for many regions without fundamental changes to the health care system, 2) adequate patient-oriented outcomes, and 3) qualitative studies along with quantitative evaluation.

The aim of this presentation is to describe a study protocol of a region-based palliative care intervention trial using the mixed-method approach: the Outreach Palliative care Trial of Integrated Model (OPTIM study) from Japan.

Methods and Design

Overview and aims

This is a regional intervention trial, consisting of a pre-post outcome study and qualitative process studies. Initially, this study was designed as a cluster randomized controlled trial, but we have decided to adopt a mixed-method design because: 1) intervention itself should be applied to all populations over the country and a clear distinction between intervention and control groups is difficult [20], 2) a concealment problem is likely to occur [2-4], and 3) the most important mission at a national level is not to clarify if one specific intervention actually changes outcomes, but to obtain comprehensive insights into how to disseminate palliative care throughout the country [17,18].

The primary aim of the pre-post outcome study is to evaluate the change in the number of home deaths, use of specialized palliative care services, patient-reported quality of palliative care, and family-reported quality of

palliative care after the regional palliative care program. The secondary aims are to explore the changes in a variety of outcomes, including the distribution of locations of death; patient- and/or family-reported quality of life, whether patients died where they actually preferred, time spent at home, satisfaction, pain, care burden; knowledge, belief, and concerns about palliative care; and knowledge, difficulties, and self-reported practice about palliative care of physicians and nurses. Qualitative process studies are performed to obtain a deep insight into how and why the regional palliative care program does or does not work.

Data for the pre-post outcome study were collected in 2007-2008 as pre-intervention data and in 2010-2011 as post-intervention data. Data for qualitative studies were collected throughout the study periods.

Ethical and scientific validity was confirmed by the institutional review board of this study and all participating institutions.

Setting

To explore the potential influence of the variations in the existing health care system, we have decided to conduct this trial in 4 regions with different palliative care systems across Japan: Tsuruoka (170,000 population, Yamagata Prefecture), Kashiwa (670,000 population, Chiba Prefecture), Hamamatsu (820,000 population, Shizuoka Prefecture), and Nagasaki (450,000 population, Nagasaki Prefecture). Kashiwa and Hamamatsu have specialized hospital palliative care teams in a cancer center and general hospitals, respectively; Nagasaki has a coordinated palliative care system for home patients in addition to hospital palliative care teams; and Tsuruoka has no formal specialized palliative care service at the beginning of the study.

Interventions

Designing interventions

Interventions were designed on the basis of literature review, preliminary survey, and discussion among the researchers and clinical practitioners from the study regions [21-33].

To construct a conceptual framework, we initially reviewed the existing domestic and international literature available to identify barriers to provide quality palliative care [21-23], and performed a preliminary survey of 8,000 general public and 8,000 medical health care providers in the 4 regions before planning the interventions [24]. The task force then drafted the intervention protocol with close collaborative with representative health care providers from the 4 regions, and has finalized intervention protocol. The intervention protocol describes the minimum requirements for this study to allow it to meet the specific situations of regions [19,20].

To deliver the intervention, each region is asked to establish a "regional palliative care center" with several local leaders, who receive a start-up 2-day workshop from the study team before intervention with continuous follow-up. Local leaders include physicians, nurses, and medical social workers who have already been working as a clinical specialist in the region. Furthermore, local leaders foster link-staffs at each regional level. To facilitate interventions, meetings among local leaders are planned to be held about 25 times during this study period; a certified community nurse visits each region and followed up by telephone and e-mail as a facilitator; and interactive conferences among link-staffs from the 4 regions are held 3 times.

The interventions include 4 areas: 1) to improve the knowledge and skills of palliative care providers, 2) to increase the availability of specialized palliative care services for community patients, 3) to coordinate community palliative care resources, and 4) to provide appropriate information about palliative care to the general public, patients, and families. We designed all interventions not to require a fundamental change in the health care system, that is, to optimize the resources within the region.

To investigate the actual implementation, we regularly monitor the intensity of interventions by telephone and visiting the intervention area [18]. In addition, in the surveys, we investigate the levels of exposure to each intervention (e.g., whether they used or noticed materials, or they participated in workshops).

Specific interventions

To improve the knowledge and skills of palliative care providers, we have prepared a pocket-size manual of palliative care (a book and videos) and 13 assessment tools (12 educational pamphlets for patients and families for each symptom, such as pain; and 1 comprehensive assessment tool). These are provided with printed materials and a web site. The local leaders are asked to disseminate these materials and hold an interactive workshop to educate them on how to use these materials [25-28].

To increase the availability of specialized palliative care services for community patients, each region is asked to establish a community palliative care team through optimizing the existing resources, because, at the time of the study, such community palliative care teams are not available in Japan. In addition, the community palliative care team provides outreach educational visits for community intuitions [29].

To coordinate community palliative care resources, each region is asked to establish a "regional palliative care center". The regional palliative care center is then asked to hold a multidisciplinary conference to develop collaborative relationships among health care workers in the region, and share and resolve problems [10,14-16].

In addition, local leaders facilitate the use of patient-held-records to maintain continuity of care [30], and facilitate the introduction of a discharge planning system for all hospitals in the region [31].

To provide appropriate information about palliative care, we have prepared a hand-sized leaflet, note-sized leaflets, posters, and DVDs about palliative care, and ask local leaders to put them in public and health care institutions [32,33]. In addition, local leaders ask public libraries to provide a "book set" (a set of 100 books about palliative care), and provide workshops for the general public. Target themes identified as barriers include the misconception about cancer pain and opioids, palliative care, and death at home [33].

Measurements

Questionnaires are sent to patients, bereaved family members, physicians, and nurses recruited consecutively following the inclusion criteria by mail. We intend to obtain the sample as a nearly representative sample of each region as much as possible.

Subjects

Patients Due to the lack of an established method to identify all cancer patients living in a specific area in Japan, we identify all hospitals in the study areas with reference to hospital lists from the Japan Hospital Association, the largest authorized organization of hospitals in Japan, and the local resource information. In the pre-intervention survey, we obtained the participation of a total of 23 of 34 hospitals treating cancer patients (8,964 beds of 11,033 beds, 81%).

Inclusion criteria are: 1) adult cancer patients with a primary tumor site in either the lung, esophagus, stomach, colon, rectum, pancreas, liver, biliary system, kidney, prostate, bladder, breast, ovary, or uterus, 2) presence of metastatic or recurrent cancer, 3) outpatient visits to the oncology department or each specialty division, such as respiratory medicine for lung cancer patients (not palliative care division only), and 4) informed of malignancy. We have determined to exclude malignancy of the brain, blood, central nervous system, neck, soft tissue, and other uncommon primary sites, due to the infrequent prevalence and increased technical difficulties in patient recruitment. We have decided to examine only patients who were informed of malignancy, because we use the term "cancer" in the questionnaire. Exclusion criteria include: 1) inability of the patient to complete the questionnaire (dementia, cognitive failure, psychiatric illness, language difficulty, or visual loss), 2) severe emotional distress of the patient as determined by the principal treating physicians, and 3) poor physical condition unable to complete the questionnaire.

Bereaved family Due to the legal limitation of a mortality-follow back survey, we identify all hospitals in the study areas in the same way as the patient survey, and general practice clinics with experience of caring for terminally ill cancer patients with reference to the local resource information.

Inclusion criteria for this bereaved family survey are: 1) bereaved adult family members of an adult cancer patient who died in the institution or at home (one family member was selected for each patient), 2) a primary tumor site of either the lung, esophagus, stomach, colon, rectum, pancreas, liver, biliary system, kidney, prostate, bladder, breast, ovary, or uterus, 3) received medical treatments on at least 3 or more days by the institution, and 4) informed of malignancy. Exclusion criteria include: 1) incapacity to complete the questionnaire (dementia, cognitive failure, psychiatric illness, language difficulty, or visual loss), 2) severe emotional distress of the family as determined by the principal treating physicians, 3) treatment-associated death or death from commodity, 4) death in intensive care units, and 5) family member unavailable.

Physicians and nurses We identify hospitals treating cancer patients in the same way as the patient survey, all general practice clinics, and district nurse services.

Inclusion criteria for the physician and nurse survey are: 1) hospital physicians and nurses working at cancer-related branches for at least 3 years (internal medicine, surgery, respiratory medicine, gastro-enterology, urology, breast cancer, gynecology, hematology, radiation oncology, clinical and medical oncology, otolaryngology, and palliative medicine), 2) representative physicians of general practice clinics, and 3) all district nurses.

Outcome Measures (Table 1)

We have determined that this study adopt 4 primary end-points due to the complex nature of the intervention: 1) number of home deaths, 2) number of patients who received specialized palliative care services, 3) patient-reported quality of palliative care, and 4) bereaved family-reported quality of palliative care [20]. In addition, we adopt multiple end-points to interpret the results from multiple perspectives.

Location of death We record the number of cancer patients who died at home, hospitals, and nursing homes from the national government registry every year, and, further, the number of patients who died in palliative care units from each palliative care unit. As the reference data, we obtain the average rate of home death in Japan during this study period. The rationale of setting the number of home deaths as one of the primary end-points is that, while many patients want to die at home, home deaths actually occur at a rate of only 6.0% in Japan [24].

Table 1 Outcome measures

	Primary end-points	Secondary end-points
Location of death	Home death	Distribution of location of death (home, hospital, palliative care units, nursing home)
Use of specialized palliative care services Patients	Number of patients who received specialized palliative care services	Backgrounds of patients referred to specialized palliative care services
Patients		
Quality of palliative care	Total score of 3 subscales of "physical care provided by physicians", "physical care provided by nurses", "psycho-existential care) of the Care Evaluation Scale	Care Evaluation Scale -physical care provided by physicians -physical care provided by nurses -psycho-existential care -help with decision-making -coordination/consistency of care
Quality of life		Good Death Inventory -physical and psychological comfort -living in a favorite place -maintaining hope and pleasure -having a good relationship with medical staff -not feeling a burden to others -having a good relationship with the family -having independence -having environmental comfort -being respected as an individual -a feeling of fulfillment at life's completion
Pain		Brief Pain Inventory
Satisfaction		Satisfaction scale
Knowledge, beliefs, and concerns		Knowledge of opioids, Beliefs about palliative care, Concerns about home care
Feelings of support and security about cancer care in the region Bereaved family members		Sense of Security Scale
Bereaved family members		
Quality of palliative care	Total score of 3 subscales of "physical care provided by physicians", "physical care provided by nurses", "psycho-existential care) of the Care Evaluation Scale	Care Evaluation Scale -same as patient, and, -help with decision making for family -family care
Quality of life of the patient (proxy)		Good Death Inventory (same as patient)
Satisfaction		Satisfaction scale
Knowledge, beliefs, and concerns		Knowledge of opioids, Beliefs about palliative care, Concerns about home care
Feelings of support and security about cancer care in the region		Sense of Security Scale
Care burden		Caregiving Consequence Inventory -Burden
Time spent at home		Time spent at home
Physicians and nurses		
		Palliative Care Knowledge Test -philosophy, pain, dyspnea, delirium, and gastrointestinal symptoms Palliative Care Difficulty Scale -expert support, alleviating symptoms, community coordination, communication in multidisciplinary teams, and communication with patients and families Palliative Care Self-reported practice Scale

Use of specialized palliative care services The rationale of setting the number of patients who received specialized palliative care services as one of the primary end-points is that multiple studies revealed the beneficial effects of specialized palliative care services on

patient outcomes [34,35], and, thus, we believe it is reasonable to assume that higher involvement in specialized palliative care services would result in the improvement in patient outcomes [36]. To calculate the number of patients who received specialized palliative care services,

we initially identify all specialized palliative care services, and ask each service to provide a complete patient list every year. The specialized palliative care service is defined as “specialized palliative care provided by palliative care specialists”, including: 1) palliative care unit, 2) hospital palliative care team, 3) community palliative care team, 4) outpatient palliative care clinic, and 4) home palliative care team.

The number of patients who received specialized palliative care services is defined as the total of number of patients listed in each specialized palliative care service, and, thus, if one patient received two types of specialized palliative care service, the number of uses of specialized palliative care services is two. Although we have acknowledged the non-duplicated counting is ideal, we gave up on this calculation because not all participating institutions allow providing patient data beyond the institutions due to privacy issues. The ratio of the number of patients who received specialized palliative care services to all cancer death was calculated.

In addition, to explore whether “early palliative care” is realized, the backgrounds of patients referred to specialized palliative care services, such as the performance status, status of disease-modifying treatment, and consultation aims, are obtained from the patient lists.

Quality of palliative care The quality of palliative care is measured by both patients and bereaved families using the Care Evaluation Scale, a well-validated and the most commonly used measurement tool to quantify the user-perceived quality of palliative care in Japan [35]. The psychometric properties are established in both patients and bereaved family members [37,38]. The full version of the Care Evaluation Scale consists of 8 subscales for patients and 10 subscales for families with a 6-point Likert-type scale from “1: improvement is not necessary at all” to “6: highly necessary”. One item example is “doctors dealt promptly with discomforting symptoms of the patient”. For this study, we have excluded 3 subscales, environment, cost, and availability, because the intervention does not intend to change these outcomes. For the primary end-points, we use 3 subscales (physical care provided by physicians, physical care provided by nurses, and psycho-existential care) as a single scale, because this directly measures the degree to which patients/family members evaluate medical professionals respond to patients’ physical and psychological distress. All subscales of the Care Evaluation Scale are used for the secondary end-points.

Quality of life Quality of life is measured by both patients and bereaved families using the Good Death Inventory, a specific measure of the quality of life of Japanese patients with advanced cancer [39,40]. We have decided to use the Good Death Inventory, not common tools such as EORTC or FACT, because: 1) we

intend to investigate broader areas of quality of life Japanese palliative care populations regard as important, especially psycho-existential components [41,42], and 2) existing quality of life measures largely depend on patient functional levels and previous studies failed to detect potentially beneficial effects of intervention [4]. The full version of this scale consists of 10 domains with a 7-point Likert-type scale from “1: strongly disagree” to “7: strongly agree”. One item example is “I am free from physical distress”. The subscale “living in a favorite place” includes “(the patient) is able to stay at his/her favorite place”, and, thus, we can analyze not only the death location but also whether the death location was a preferred place of death of the patients [2].

Satisfaction Satisfaction of the patient and family with medical care is measured using a single item scale: “Are you satisfied with the medical care you currently receive?” with a 6-point Likert-type scale varying from “1: very dissatisfied” to “6: very satisfied”.

Pain intensity Pain intensity of the patients is measured using the Japanese version of the Brief Pain Inventory, with a score given for the pain at its worst (0-10), at its best (0-10) and a score for the average pain felt (0-10) over the previous 24 hours. The reliability and validity in Japanese populations has been established [43].

Knowledge, perceptions, and concerns about palliative care Knowledge, perceptions, and concerns about palliative care of the patients and families is measured using 10 items, similar to previous surveys [33], on a 5-point Likert-type scale from 1:strongly disagree to 5: strongly agree. Knowledge of opioids is examined using 2 items: “opioids can relieve most pain caused by cancer” and “opioids are addictive and/or shorten life”. Beliefs about palliative care are examined using 3 items: “palliative care relieves pain and distress”, “palliative care is provided along with chemotherapy and/or radiation therapy”, and “palliative care is only for terminally ill patients”. Concerns about homecare are examined based on 5 items: “pain can be alleviated as effectively through home-visit services as it can at the hospital”, “home - visit services cannot respond to sudden changes in a patient’s condition”, “it is hard to find home-visiting physicians”, and “being taken care of at home puts a burden on the family”.

Feelings of support and security regarding cancer care in the region Feelings of support and security regarding cancer care in the region are measured by patients and families using the newly developed Sense of Security Scale [44]. This is 5-item scale to assess feelings of support and security concerning cancer care in a region. One item example is “I would feel secure as a variety of medical care services are available in the region”.

Care burden Care burden is measured using the Caregiving Consequences Inventory [45]. The Caregiving

Consequences Inventory is developed to quantify caregiving consequences from a bereaved family member's perspective, and it consists of 4 positive domains and 1 burden domain. For this study, the burden domain is used.

Time spent at home Due to a lack of administrative data available to calculate time spent at home, we ask bereaved family members the time spent at home during the last 1 and 3 months.

Knowledge, difficulty, and self-perceived practice of palliative care of physicians and nurses Physician- and nurse-reported knowledge is measured using Palliative Care Knowledge Test [46]. This scale consists of 5 subscales, with correct, incorrect, and do not know responses.

Physician- and nurse-reported difficulty of palliative care is measured with the Palliative Care Difficulty Scale, a validated tool to quantify the levels of difficulty when health professionals provide palliative care [47]. This scale consists of 5 subscales with a 5-point Likert-type scale from 1: never to 5: very much. One item example is "it is difficult to get support from experts on alleviating symptoms".

Physician- and nurse-reported self-perceived practice is measured employing the Palliative Care Self-reported Practice Scale, a validated tool to quantify the levels of adherence to recommended practices in palliative care fields⁴⁷. This scale consists of 6 subscales with a 5-point Likert-type scale from 1: never to 5: very much. One item example is "I routinely inquire about the family's concerns in the dying phase".

Quality indicators As quality indicators as region-level palliative care, we collect 20 quality indicators from nation-level administrative database, such as opioids consumption, the number of home care service, the number of palliative care specialists, and the number of palliative care units.

Qualitative studies

Qualitative studies consisting of 3 studies.

Descriptive study

A descriptive study is performed to describe the process in developing regional palliative care in each local context. The study methodology is descriptive case studies, and this includes a variety of materials each region has made or arranged for local interventions.

Interview study

This study is performed to understand the process of how and why the regional palliative care program makes changes in the region. The ultimate purpose of this study is to propose a model for shaping regional palliative care. The research methodology is a grounded theory approach, and the data source is in-depth interviews with health care professionals.

Systematic collection of barriers and potential resolutions

This study is performed to systemically identify the barriers of palliative care at a regional level and potential resolutions. The research methodology is content analyses, and the data source is multiple focus-groups repeatedly conducted during the entire study period, field notes, and documents obtained.

Sample size calculations and analyses

As this study have 4 primary-end-points, i.e., the number of home deaths, use of specialized palliative care services, patient-reported quality of palliative care, and family-reported quality of palliative care, we have set alpha error of 0.0125 (two-sided) by the Bonferroni correction for multiple comparisons. All variables are compared between before and after the interventions using the Student t-test and Chi-square test, where appropriate.

Patient-reported quality of palliative care and family-reported quality of palliative care

To detect 0.2 effect size (one-fifth difference of standard deviation) for quality of palliative care (the Care Evaluation Scale) under statistical power of 0.8, 558 responses for each pre-intervention and post-intervention period is required for the analyses³⁵. We have thus determined that 1500 patients and bereaved family members should be surveyed at each time in consideration of the estimated response rate (40-60%) and missing values (10%) [35].

The number of home deaths and use of specialized palliative care services

We first assumed 6% and 8% as each pre-intervention value from the national data, respectively, and we expected to achieve 12% and 20% as meaningful increases after the intervention, respectively; and this lead to the calculated sample size of 506 and 186 at the each point, respectively. In practice, as we survey all cancer death in 4 regions (5000), the sample size is sufficient.

Discussion

This study is, to our knowledge, one of the most comprehensive evaluations of a region-based palliative care intervention program. This study has 3 major unique aspects.

First, as an outcome study, this study measures a wide range of outcomes, enabling comprehensive understanding and interpretation of the results. Especially, this study is outstanding in terms of: 1) we can obtain patient and family views as a nearly representative sample of advanced cancer patients and bereaved family members in the region; 2) we measure quality of care and quality of life specifically designed for palliative care populations, not heavily depending on the functional

status; 3) we can know whether a patient actually died where they preferred, not only the location of death itself; and 4) we quantitatively measure the change in physicians' and nurses' knowledge, difficulties, and self-reported practice at regional levels, especially difficulties in communicating among local health care professionals. These efforts are all novel, and would provide useful insights to disseminate palliative care at regional levels as well as important information for designing future intervention studies in this area.

Second, this study adopts a qualitative process method. Rich description in each local context, understanding how the program works in shaping community palliative care through the grounded theory approach, and systematic collection of barriers and resolution will lead to obtaining deep insights into how quality community palliative care is developed. We will use the findings in two ways, namely as a practical guidance for clinicians and as an integrated information resource for policy makers.

Third, the intervention applied in this study is without a fundamental change in health care systems. This means the findings from this study would be applicable to all regions in Japan and probably in other countries, and clarify what is necessary for community palliative care as a basis. In other words, after completing this study, we can plan a randomized controlled trial using "novel" intervention requiring fundamental changes in the health care system.

The study analyses will be completed by the end of 2013, and a comprehensive understanding of the findings of this study will contribute to a deeper insight into how to develop community palliative care.

Acknowledgements

This study is funded by the Third Term Comprehensive Control Research for Cancer Health and Labour Sciences Research Grant.

Author details

¹Department of Palliative and Supportive Care, Palliative Care Team, and Seirei Hospice, Seirei Mikatahara, General Hospital 3453 Mikatahara-cho, Hamamatsu, Shizuoka 433-8558, Japan. ²Department of Adult Nursing/Palliative Care Nursing, School of Health Sciences and Nursing, Graduate, School of Medicine, The University of Tokyo, 7-3-1, Hongo, Bunkyo-ku, Tokyo 113-0033, Japan. ³Department of Adult Nursing/Palliative Care Nursing, School of Health Sciences and Nursing, Graduate, School of Medicine, The University of Tokyo, 7-3-1, Hongo, Bunkyo-ku, Tokyo 113-0033, Japan. ⁴Psycho-Oncology Division, Research Center for Innovative Oncology, National Cancer Center Hospital East 6-5-1, Kashiwanoha, Kashiwa, Chiba 277-8577, Japan. ⁵Department of Medical Social Service, Center for Palliative and Supportive Care, Graduate School, University of Tsukuba, 1-1-1 Ten-nohdai, Tsukuba 305-8575, Japan. ⁶Shirahige Clinic, 1-13-28, Katafuchi, Nagasaki, Nagasaki 850-0003, Japan. ⁷Faculty of Policy Management, Keio University, 5322 Endo, Fujisawa-shi, Kanagawa 252-8520, Japan. ⁸Graduate School of Human Sciences; Center for the Study of Communication-Design; Department of Complementary and Alternative Medicine, Graduate School of Medicine, Osaka University, 1-2, Yamadaoka, Suita, Osaka 565-0871, Japan. ⁹Department of Palliative Medicine and Psycho-Oncology, National Cancer Center, 5-1-1 Tsukiji, Chuo-ku, Tokyo 104-0045, Japan. ¹⁰Research Center for

Development of Nursing Practice, St. Luke's College of Nursing 3-8-5 Tsukiji, Chuo-ku, Tokyo 104-0045, Japan. ¹¹Division of Respiratory Disease, Head of Regional Support, Kumamoto Takumadai Hospital, 1-14-27 Onoue, Kumamoto-city, Kumamoto 862-0913, Japan. ¹²Department of Clinical Trial Data Management, Graduate School of Medicine, The University of Tokyo, Hospital, 7-3-1, Hongo, Bunkyo-ku, Tokyo 113-0033, Japan. ¹³School of Medicine, Tokai University, 143 Shimokasuya, Isehara, Kanagawa 259-1143, Japan.

Authors' contributions

TMO led the drafting of this paper and development of the protocol. MMI and TY co-designed the protocol from the view point of statistical specialists. AY and TMO co-designed qualitative process studies. NA, YK, MA, KH, MMa, MY, and YS co-designed the intervention protocol as specialists and/or local leaders. KE organized the study structure, funded all aspects of this study, and supervised all phases of this study. All authors read and approved the final draft.

Competing interests

The authors declare that they have no competing interests.

Received: 8 November 2011 Accepted: 11 January 2012

Published: 11 January 2012

References

1. World Health Organization: *National cancer control programmes: Policies and managerial guidelines second edition*. Geneva, WHO 2002.
2. Jordhøy MS, Fayers P, Saltnes T, Ahlner-Elmqvist M, Jannert M, Kaasa S: A palliative-care intervention and death at home: a cluster randomised trial. *Lancet* 2000, **356**:888-893.
3. Ringdal GI, Jordhøy MS, Kaasa S: Family satisfaction with end-of-life care for cancer patients in a cluster randomized trial. *J Pain Symptom Manage* 2002, **24**:53-63.
4. Jordhøy MS, Fayers P, Loge JH, Ahlner-Elmqvist M, Kaasa S: Quality of life in palliative cancer care: results from a cluster randomized trial. *J Clin Oncol* 2001, **19**:3884-3894.
5. Fassbender K, Fainsinger R, Brenneis C, Brown P, Braun T, Jacobs P: Utilization and costs of the introduction of system-wide palliative care in Alberta, 1993-2000. *Palliat Med* 2005, **19**:513-520.
6. Fainsinger RL, Bruera E, MacMillan K: Innovative palliative care in Edmonton. *Can Fam Physician* 1997, **43**:1983-1992.
7. Dudgeon DJ, Knott C, Chapman C, Coulson K, Jeffery E, Preston S, Eichholz M, Van Dijk JP, Smith A: Development, implementation, and process evaluation of a regional palliative care quality improvement project. *J Pain Symptom Manage* 2009, **38**:483-495.
8. Dudgeon DJ, Knott C, Eichholz M, Gerlach JL, Chapman C, Viola R, Van Dijk J, Preston S, Batchelor D, Bartfay E: Palliative care integration project (PCIP) quality improvement strategy evaluation. *J Pain Symptom Manage* 2008, **35**:573-582.
9. Gómez-Batiste X, Porta-Sales J, Pascual A, Nabal M, Espinosa J, Paz S, Minguell C, Rodríguez D, Esperalba J, Stjernswärd J, Geli M: Palliative Care Advisory Committee of the Standing Advisory Committee for Socio-Health Affairs, Department of Health, Government of Catalonia. Catalonia WHO palliative care demonstration project at 15 years (2005). *J Pain Symptom Manage* 2007, **33**:584-590.
10. Shaw KL, Clifford C, Thomas K, Meehan H: Improving end-of-life care: a critical review of the Gold Standards Framework in primary care. *Palliat Med* 2010, **24**:317-329.
11. Munday D, Mohmood K, Dale J, King N: Facilitating good process in primary palliative care: does the Gold Standards Framework enable quality performance? *Fam Pract* 2007, **24**:486-494.
12. Dale J, Petrova M, Munday D, Koistinen-Harris J, Lall R, Thomas K: A national facilitation project to improve primary palliative care: impact of the Gold Standards Framework on process and self-ratings of quality. *Qual Saf Health Care* 2009, **18**:174-180.
13. Walsh C, Caress A, Chew-Graham C, Todd C: Implementation and impact of the Gold Standards framework in community palliative care: a qualitative study of three primary care trusts. *Palliat Med* 2008, **22**:736-743.
14. Kelley ML: Developing rural communities' capacity for palliative care: a conceptual model. *J Palliat Care* 2007, **23**:143-153.

15. Masso M, Owen A: Linkage, coordination and integration. Evidence from rural palliative care. *Aust J Rural Health* 2009, **17**:263-267.
16. Nibbakh-Van de Sande CV, van der Rijt CC, Visser AP, ten Voorde MA, Pruyn JF: Function of local networks in palliative care: A dutch view. *J Palliat Med* 2005, **8**:808-816.
17. Lewin S, Glenton C, Oxman AD: Use of qualitative methods alongside randomised controlled trials of complex healthcare interventions: methodological study. *BMJ* 2009, **339**:b3496.
18. Oakley A, Strange V, Bonell C, Allen E, Stephenson J, RIPPLE Study Team: Process evaluation in randomised controlled trials of complex interventions. *BMJ* 2006, **332**:413-416.
19. Hawe P, Shiell A, Riley T: Complex interventions: how "out of control" can a randomised controlled trial be? *BMJ* 2004, **328**:1561-1563.
20. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M, Medical Research Council Guidance: Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* 2008, **337**:a1655.
21. Mitchell G: How well do general practitioners deliver palliative care? A systematic review. *Palliat Med* 2002, **16**:457-464.
22. Ahmed N, Bestall JC, Ahmedzai SH, Payne SA, Clark D, Noble B: Systematic review of the problems and issues of accessing specialist palliative care by patients, carers and health and social care professionals. *Palliat Med* 2004, **18**:525-542.
23. Miyashita M, Sanjo M, Morita T, Hirai K, Kizawa Y, Shima Y, Shimoyama N, Tsuneto S, Hiraga K, Sato K, Uchitomi Y: 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.
24. [<http://gankanwa.jp/tools/pro/survey.html>], (in Japanese).
25. Farmer AP, Légaré F, Turcot L, Grimshaw J, Harvey E, McGowan JL, Wolf F: Printed educational materials: effects on professional practice and health care outcomes. *Cochrane Database Syst Rev* 2008, **3**: CD004398.
26. Goldberg GR, Morrison RS: Pain management in hospitalized cancer patients: A systematic review. *J Clin Oncol* 2007, **25**:1792-1801.
27. Alvarez MP, Agra Y: Systematic review of educational interventions in palliative care for primary care physicians. *Palliat Med* 2006, **20**:673-683.
28. Forsetlund L, Bjørndal A, Rashidian A, Jamtvedt G, O'Brien MA, Wolf F, Davis D, Odgaard-Jensen J, Oxman AD: Continuing education meetings and workshops: effects on professional practice and health care outcomes. *Cochrane Database Syst Rev* 2009, **2**: CD003030.
29. O'Brien MA, Rogers S, Jamtvedt G, Oxman AD, Odgaard-Jensen J, Kristoffersen DT, Forsetlund L, Bainbridge D, Freemantle N, Davis DA, Haynes RB, Harvey EL: Educational outreach visits: effects on professional practice and health care outcomes. *Cochrane Database Syst Rev* 2007, **4**: CD000409.
30. Gysels M, Richardson A, Higginson IJ: Does the patient-held record improve continuity and related outcomes in cancer care: a systematic review. *Health Expect* 2006, **10**:75-91.
31. Fukui S, Fujita J, Tsujimura M, Sumikawa Y, Hayashi Y, Fukui N: Late referrals to home care service affecting death at home in advanced cancer patients in Japan: a nationwide survey. *Ann Oncol* 2011, **22**:2113-2120.
32. Bala M, Strzeszynski L, Cahill K: Mass media interventions for smoking cessation in adults. *Cochrane Database Syst Rev* 2008, **1**: CD004704.
33. Morita T, Miyashita M, Shibagaki M, Hirai K, Ashiya T, Ishihara T, Matsubara T, Miyoshi I, Nakaho T, Nakashima N, Onishi H, Ozawa T, Suenaga K, Tajima T, Akechi T, Uchitomi Y: 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.
34. Higginson IJ, Finlay IG, Goodwin DM, Hood K, Edwards AG, Cook A, Douglas HR, Normand CE: 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.
35. Miyashita M, Morita T, Hirai K: Evaluation of end-of-life cancer care from the perspective of bereaved family members: the Japanese experience. *J Clin Oncol* 2008, **26**:3845-3852.
36. Casarett D, Karlawish J, Morales K, Crowley R, Mirsch T, Asch DA: Improving the use of hospice services in nursing homes: a randomized controlled trial. *JAMA* 2005, **294**:211-217.
37. 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.
38. Miyashita M, Wada M, Morita T, Matoba M, Tsuneto S, Shima Y: Reliability and Validity of the Care Evaluation Scale patient version. *Proceedings of the 15th congress of Japanese Society of Palliative Medicine, Tokyo* 2010, **165**.
39. Miyashita M, Morita T, Sato K, Shima Y, Uchitomi Y: Good Death Inventory: A measure for evaluating good death from the bereaved family member's perspective. *J Pain Symptom Manage* 2008, **35**:486-498.
40. Miyashita M, Wada M, Morita T, Matoba M, Tsuneto S, Shima Y: Reliability and Validity of the Good Death Inventory patient version. *Proceedings of the 15th congress of Japanese Society of Palliative Medicine, Tokyo* 2010, **165**.
41. 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.
42. 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.
43. Uki J, Mendoza T, Cleeland CS, Nakamura Y, Takeda F: A brief cancer pain assessment tool in Japanese: the utility of the Japanese Brief Pain Inventory-BPI-J. *J Pain Symptom Manage* 1998, **16**:364-373.
44. Igarashi A, Miyashita M, Morita T, Akizuki N, Akiyama M, Shirahige Y, Eguchi K: A scale for measuring feelings of support and security about cancer care in a region of Japan: a potential new endpoint of palliative care. *J Pain Symptom Manage* 2011.
45. Sanjo M, Morita T, Miyashita M, Shiozaki M, Sato K, Hirai K, Shima Y, Uchitomi Y: Caregiving Consequences Inventory: a measure for evaluating caregiving consequences from the bereaved family member's perspective. *Psychooncology* 2009, **18**:657-666.
46. Nakazawa Y, Miyashita M, Morita T, Umeda M, Oyagi Y, Ogasawara T: The palliative care knowledge test: reliability and validity of an instrument to measure palliative care knowledge among health professionals. *Palliat Med* 2009, **23**:754-766.
47. Nakazawa Y, Miyashita M, Morita T, Umeda M, Oyagi Y, Ogasawara T: The palliative care self-reported practices scale and the palliative care difficulties scale: reliability and validity of two scales evaluating self-reported practices and difficulties experienced in palliative care by health professionals. *J Palliat Med* 2010, **13**:427-437.

Pre-publication history

The pre-publication history for this paper can be accessed here:
<http://www.biomedcentral.com/1472-684X/11/2/prepub>

doi:10.1186/1472-684X-11-2

Cite this article as: Morita et al.: A region-based palliative care intervention trial using the mixed-method approach: Japan OPTIM study. *BMC Palliative Care* 2012 **11**:2.

Submit your next manuscript to BioMed Central and take full advantage of:

- Convenient online submission
- Thorough peer review
- No space constraints or color figure charges
- Immediate publication on acceptance
- Inclusion in PubMed, CAS, Scopus and Google Scholar
- Research which is freely available for redistribution

Submit your manuscript at
www.biomedcentral.com/submit



● 特別寄稿 ●

がん専門病院が地域緩和ケアの向上のために
取り組んでいることと課題木下 寛也^{*1} 渡邊 敏^{*2} 小笠原鉄郎^{*3} 橋本 淳^{*4} 松尾 直樹^{*5}
三宅 智^{*6} 森田 達也^{*7}

[Jpn J Cancer Chemother 39(10): 1527-1532, October, 2012]

What Do Cancer Centers do to Improve Community Palliative Care?: Hiroya Kinoshita^{*1}, Satoshi Watanabe^{*2}, Tetsuo Ogasawara^{*3}, Atsushi Hashimoto^{*4}, Naoki Matsuo^{*5}, Satoshi Miyake^{*6} and Tatsuya Morita^{*7} (^{*1}Dept. of Palliative Medicine and Psycho-Oncology, National Cancer Center Hospital, East, ^{*2}Division of Palliative Medicine, Chiba Cancer Center Hospital, ^{*3}Dept. of Palliative Care, Miyagi Cancer Center, ^{*4}Dept. of Palliative Medicine, Aichi Cancer Center Aichi Hospital, ^{*5}Dept. of Palliative Care, Saitama Cancer Center, ^{*6}Dept. of Palliative Medicine, Tochigi Cancer Center, ^{*7}Dept. of Palliative and Supportive Care, Seirei Mikatahara General Hospital)

Summary

This study's purpose was to gain insight into practical strategies for improving community palliative care in Japan. Focus groups were held involving physicians, medical social workers, and nurses of 6 cancer centers, and the collected data were qualitatively analyzed. A total of 19 categories were examined. They were related to 1) education for medical health care professionals about palliative care, 2) public education about palliative care, 3) specialized palliative care service, and 4) constructing a community palliative care network. Additionally, 7 categories related to medical and social systems were analyzed. The list proposed in this study may be effective for systematically understanding approaches to improve community palliative care. The implementation of nationwide focus groups which rapidly disclose their results may contribute to improving regional palliative care at a national level. Key words: Palliative care, Cancer center, Community palliative care (Received Dec. 28, 2011/Accepted Feb. 22, 2012)

要旨 本研究の目的は、がん専門病院が地域緩和ケアの向上のためにやっていること、課題、解決策を収集することにより、地域緩和ケアを向上させる方策の具体的な工夫に関する洞察を得ることである。六つのがん専門病院の医師、医療ソーシャルワーカー、看護師を対象としたフォーカスグループを行い、質的分析を行った。緩和ケアの知識の普及、患者・家族・住民への啓発、専門的な緩和ケアの提供、緩和ケアの連携の促進についての取り組みとして合計19カテゴリーが、現場では有効な解決策が見当たらない課題として合計7カテゴリーが同定された。本研究で作成されたリストは各活動を行う上での工夫を系統的に整理することに役立つと考えられる。さらに、同様のフォーカスグループを全国的に行いその結果を迅速に公開する仕組みを作ることは、全国水準での地域緩和ケアの向上に貢献する可能性がある。

*1 国立がん研究センター東病院・緩和医療科・精神腫瘍科

*2 千葉県がんセンター・緩和医療科

*3 宮城県立がんセンター・緩和ケア部

*4 愛知県がんセンター愛知病院・緩和ケア科

*5 埼玉県立がんセンター・緩和ケア科

*6 栃木県立がんセンター・緩和医療部

*7 聖隷三方原病院・緩和支持治療科

連絡先: 〒 277-8577 千葉県柏市柏の葉 6-5-1 国立がん研究センター東病院・緩和医療科・精神腫瘍科
木下 寛也

緒 言

地域での緩和ケアの普及が求められている^{1,2)}。地域での緩和ケアを普及するために、がん専門病院を含むがん診療連携拠点病院は中心的な役割を担うことが期待されている。わが国の緩和ケアの課題として、医師や看護師の緩和ケアの知識・技術が不十分であること、患者・家族・住民の緩和ケアの認識が適切ではないこと、専門的な緩和ケアを提供する体制にないこと、地域で緩和ケアを提供するための連携体制が構築されていないことがあげられている³⁾。それぞれに対して、緩和ケアの知識の普及、患者・家族・住民への啓発、専門的な緩和ケアの提供、緩和ケアの連携の促進が行われており、国のレベルとしては、PEACEプロジェクト、オレンジバールンプロジェクト、緩和ケアチームの保険適応などの対応が具体的にとられている⁴⁾。一方、地域のがん診療連携拠点病院ごとにも様々な取り組みが行われており、取り組む上で様々な工夫が行われていると考えられる。地域や施設を越えて地域緩和ケアを普及するための方策を共有することは、他の地域でうまくいっている方法から学んだり、新しい方法を取り入れたりすることに有用な可能性がある⁵⁾。しかしこれまでに、がん専門病院が地域緩和ケアの普及のためにどのような取り組みをしているかを複数地域の担当者を対象として収集した研究はない。本研究では、がん専門病院が地域緩和ケアの向上のために行っていること、課題、今後の解決策を収集することにより、地域緩和ケアを向上させる方策の具体的な工夫に関する洞察を得ることである。

I. 対象・方法

六つのがん専門病院の医師、医療ソーシャルワーカー、看護師を対象としたフォーカスグループを行った。参加者の構成は、医師6名(全員が緩和ケア担当医)、医療ソーシャルワーカー6名、看護師が5名(退院支援・地域連携担当看護師4名、緩和ケア病棟師長1名)であった。職種別に三つのグループに分け、「がん専門病院として地域緩和ケアの四つの側面(緩和ケアの知識の普及、患者・家族・住民への啓発、専門的な緩和ケアの提供、緩和ケアの連携の促進)のそれぞれについて今取り組んでいること、課題、今後の解決策を尋ねた。フォーカスグループは180分行い、録音したものを逐語記録とした。逐語記録は延べ176,562語であった。

最初に、臨床心理士2名が独立して緩和ケア医師(MK)の助言の下に、「緩和ケアの知識の普及、患者・家族・住民への啓発、専門的な緩和ケアの提供、緩和ケアの連携の促進について、今取り組んでいること、課題、

今後の解決策」が述べられた部分を意味単位として抽出し、意味内容の類似性から分類し、カテゴリーを作成した。次に、緩和ケア領域での研究の経験の豊富な緩和ケア医師(TM)のスーパーバイズの下に議論して一致させた。今取り組んでいること、課題、今後の解決策については、それぞれが一体となって語られていることが多かったため、分析では四つの側面ごとに取り組んでいることと解決策をまとめてカテゴリー化した。解決策が提示されなかったものは、まとめて「現場では有効な解決策が見当たらない課題」として分類した。本研究の目的はテーマの収集であるため、カテゴリーの数の集計は行わなかった。取り組み・解決策の背景や理由が語られている場合には、(～のため)と表記して明確化した。データを「」で示し、カテゴリーを【】で示した。

研究参加者に自由意思での参加であることなどについての同意を文章で得た後に、解析は個人情報秘匿に留意して行われた。

II. 結 果

緩和ケアの知識の普及、患者・家族・住民への啓発、専門的な緩和ケアの提供、緩和ケアの連携の促進についての取り組みとして合計19カテゴリーが、現場では有効な解決策が見当たらない課題として合計7カテゴリーが同定された。

緩和ケアの知識の普及のための取り組みとしては、院内の勉強会などの【勉強会を行う】が主であったが、内容や方法の様々な工夫があげられた(表1)。多くの施設が、【すでにあるものを利用する】ことの重要性について言及した。すなわち、独自に研修会や講演会を行うのではなく、すでにある研修会を利用する、院内の勉強会を地域に公開することによって負担を減らしながら同じ程度の効果を得られることが語られた。また【内容を工夫する】では、特に看護教育において、カリキュラムがスケジュールに沿って行われることや、修了証を準備することが看護師の動機づけになることが述べられた。方法も講義のみではなく、グループワーク、事例検討、病棟での実習など様々な方法をとることが必要であると述べられた。地域の緩和ケアの向上という点では、【診療所医師のアシストをする訪問看護師や保険薬局薬剤師を対象とする】ことが意識されていた。すなわち、通常の診療所医師は1年間に体験するがん患者の頻度が少ないと考えられるため、診療所医師よりもむしろ訪問看護師や保険薬局薬剤師の緩和ケアの知識を向上することで、チーム全体としての緩和ケアの知識・技術の向上を行うことが重要であるとの考えが述べられた。

患者・家族・住民への啓発のための取り組みとしては、

表1 緩和ケアの知識の普及のための取り組み

【勉強会を行う】
・緩和ケアチームが中心に院内の勉強会を行う
・リンクナースで主催して勉強会を行う
・リンクスタッフどうしの交流会を行う
【すでにあるものを利用する】
・看護協会の e-learning を行っている
・新しく企画するよりも既存のものに組み込んでいく
・院内の勉強会を地域に対して公開して行っている
【内容を工夫する】
・日常的に経験することを扱う
・看護師のラダーに沿って方法（講義やグループワークなど）を変える
・基礎編、応用編それぞれに修了証をだす。認定看護師の受験に対応できるようにする
・講義だけでなく、事例紹介、事例についてのディスカッションを中心にする
・講義だけでなく、病棟での見学・実習を組み合わせる
・1年分で内容が網羅できるようにスケジュールをあらかじめ決めて行っている
【診療所医師のアシストをする訪問看護師や保険薬局薬剤師を対象とする】
・（年間の体験数の少ない診療所医師へ具体的な提言ができるように）訪問看護師への教育を行っている
・病院の緩和ケア認定看護師が訪問看護ステーションにでかけて出前講義を行っている
・（年間の体験数の少ない診療所医師へ具体的な提言ができるように）保険薬局薬剤師への教育を行っている
・保険薬局薬剤師の勉強会では、診療所医師も一緒に参加を依頼する

カテゴリーに相当する代表的な項目を示す

表2 患者・家族・住民への啓発のための取り組み

【マテリアルを作成する】
・ポスター、ホームページを作成する
・新聞に掲載を依頼する
【既存のマテリアルを活用する】
・NHK小冊子「ホスピスってなあに？」を設置する
・緩和ケアに関する書籍を設置する
・「患者必携」を活用する
【公開講座やイベントを行う】
・市民公開講座を行っている
・がん予防・化学療法中などのための健康料理教室を行っている
【既存のイベントや活動に参加する】
・市民の健康イベントで講演や相談ブースをだしている
・中学生など向けの命の授業などに参加する
・市民の集まりに病院職員がボランティアとして参加する
【患者会を行ったり、患者会と連携する】
・患者会や患者サロン、遺族会を行う
・患者会との懇談会を行う
・患者会に場所を提供して運営は患者会に依頼する
【病院施設を公開する】
・病院全体を知ってもらうオープンキャンパスを行う
・院内図書館を自由なスペースとして開放する
【日々の臨床を「啓発」であるにとらえる】
・今の介護世代が高齢化社会の患者になるので、介護者が自宅でもできたと思える体験を積めるように意識している

カテゴリーに相当する代表的な項目を示す

ポスターなどの【マテリアルを作成する】、【既存のマテリアルを活用する】、【公開講座やイベントを行う】、【既存のイベントや活動に参加する】といった一般的な啓発活動が述べられた(表2)。加えて、多くの施設で、患者会との多様な連携、すなわち自施設で患者会を行うばかりではなく、患者会の運営についての懇談会を行ったり、

場所の提供を行い運営は患者会に任せるなど多様な方法が【患者会を行ったり、患者会と連携する】として語られた。この他、大学のオープンキャンパスなど【病院施設を公開する】ことも啓発活動としてあげられた。一方、「今の介護世代が高齢化社会の患者になるので介護者が自宅でもできたと思える体験を積めるように意識してい

表 3 緩和ケアの連携の促進のための取り組み

<p>【病院からの退院支援を強化する】</p> <ul style="list-style-type: none"> ・退院前カンファレンスを行う ・(退院前カンファレンスを行う時間調整がたいへんなので) サマリーを細かく書く、出席できる医師や看護師が状況を聞いていくことで対応する ・退院時のサマリーに外来で継続看護をして欲しいことをリストしている ・(患者の見捨てられた感じを減らし、自宅での生活のイメージをもつために) 退院後に病棟看護師が患者の自宅に行く ・医療福祉相談、看護相談、地域連携を一つの部署にする <p>【外来での在宅支援を強化する】</p> <ul style="list-style-type: none"> ・(外来での在宅移行が多いため)「退院調整看護師」を「在宅支援選任看護師」と名称を変える ・医師1名、看護師2名を専従とするサポータティブセンターを設置し、治療早期からのかかりつけ医師の紹介など在宅リソースへのつなぎをしている ・外来で専従の看護師が困っていきそうな人に積極的に声をかけている <p>【在宅療養中の患者の情報共有とバックアップベッドの確保を行う】</p> <ul style="list-style-type: none"> ・訪問看護師と患者の状況について書面など公式なものにかかわらず情報交換をこまめに行う ・在宅にいる患者の緊急時の対応ベッドとして緩和ケア病棟を常に1~2床空けている <p>【病院医師・看護師が在宅を念頭に置いた診療やケアができるように教育プログラムを作る】</p> <ul style="list-style-type: none"> ・院内のセミナーや教育課程に、緩和ケアのみではなく、退院支援に関する内容を含む ・病棟看護師が訪問看護ステーションに実習に行く ・(在宅看護がカリキュラムに入っていなかった時期の看護師に在宅の視点がないことが多いので) 師長・副師長が訪問看護実習をする <p>【地域で一緒にみた患者の経過を共有する】</p> <ul style="list-style-type: none"> ・訪問看護を受けた患者の写真を病棟看護師や医師にみせる <p>【病院スタッフと地域スタッフとの情報交換の場を増やす】</p> <ul style="list-style-type: none"> ・(診療所医師の特徴を知って患者に合う診療所を紹介できるように) 訪問看護ステーション看護師と病院看護師・地域連携室で会う機会を増やしている ・(お互いをよく知るために) 在宅医懇話会・ピースプロジェクトなどを利用して集まりをもつ ・地域緩和ケアに関心のある医療福祉従事者のメーリングリストを運営している ・医師会とがん専門病院とで会合をもっている ・診療所医師・看護師を緩和ケア病棟で実習・研修する

カテゴリーに相当する代表的な項目を示す

る」のように、特に啓発活動というものではなく【日々の臨床を「啓発」である」とらえる】意見もあった。多くの参加者が患者・家族に対する「緩和ケアの啓発」の困難について述べ、「患者がいちばん否定したいことを受け入れるのは難しい」、「医療者よりも患者や家族の拒否感が大きい」などと表現した。

専門的な緩和ケアの提供のための取り組みとしては、多くはあげられなかったが、【緩和ケア病棟の役割を見直す】として、「(より多くの患者が使用できるように)緩和ケア病棟は長期の療養場所ではないが緊急入院は受けられることを説明し、短期入院の方針としている」、「長期療養を希望する場合には、がん専門病院以外のホスピスを紹介している」ことがあげられた。また、地域連携バスの一環として【緩和ケア専門家へのホットラインを設置】したが、利用は少ないとの意見があった。

緩和ケアの連携の促進のための取り組みとして、退院前カンファレンスを行うなどの【病院からの退院支援を強化する】、外来に専従の人員を配置したり専門部署を作るなどの【外来での在宅支援を強化する】、在宅療養中の患者のサポートとして【在宅療養中の患者の情報共有

とバックアップベッドの確保を行う】、および【病院医師・看護師が在宅を念頭に置いた診療やケアができるように教育プログラムを作る】があげられた(表3)。また、地域でのネットワークを作る取り組みとして、自宅に帰った患者の自宅での様子を写真で報告する仕組みを作るといった【地域で一緒にみた患者の経過を共有する】や、各種ミーティング・メーリングリスト・現場での研修を通じて【病院スタッフと地域スタッフとの情報交換の場を増やす】ことがあげられた。

一方、現場では有効な解決策が見当たらない課題としては、【経済的負担】、【医療福祉従事者の負担】、【在宅医療を提供する医師・看護師の不足】、救急搬送時の問題として【急な状態悪化時の対応】、必要な時に患者情報をやり取りできない【個人情報の保護】、新しく作成したツールは運用するのが難しい【ツールの運用の難しさ】があげられた(表4)。

このうち、【在宅医療を提供する医師・看護師の不足】については、現場では「一人ずつ開拓している」、「新しい先生よりも確実な先生と組んで地域でもできるという感覚を増やす」、「診療所医師5名くらいでチームとして

表4 現場では有効な解決策が見当たらない課題

<p>【経済的負担】</p> <ul style="list-style-type: none"> ・医療費が高く、本来必要な医療やサービスを受けられない ・在宅療養は時間で費用が違うため患者が長い時間のコミュニケーションを希望しないことがある <p>【医療福祉従事者の負担】</p> <ul style="list-style-type: none"> ・スタッフの疲弊が激しい ・集まりは夕方からになるため仕事が終わらないか、時間外になる <p>【在宅医療を提供する医師・看護師の不足】</p> <ul style="list-style-type: none"> ・在宅診療を行う医師の総数が変わらないので負担が偏っている ・在宅医療のスキルのある医師は人気があるので偏っていく ・かかりつけ医師がいる患者が少なく、病院医師がかかりつけのことが多い ・診療所は立場が弱く患者からの不満があると意欲が落ちる <p>【急な状態悪化時の対応】</p> <ul style="list-style-type: none"> ・急な状態悪化時に救急搬送される <p>【個人情報の保護】</p> <ul style="list-style-type: none"> ・個人情報保護のため訪問看護ステーションからでは病院から（患者に直接聞けない）情報を入手できない ・FAXが確実に相手に届くかわからないので情報を聞けないことがある <p>【療養場所の不足】</p> <ul style="list-style-type: none"> ・（質の高い療養場所がないため）緩和ケア病棟から転院は難しい ・（療養場所がないため）緩和ケア病棟が療養病床のようになる ・（緩和ケア病棟がないため）緩和ケア病棟の待ち日数が長く、入れない患者がいる ・（大学の系列が違うため）療養場所が見つからない ・地域により差が大きく、人口とリソースの比率が一致していない <p>【ツールの運用の難しさ】</p> <ul style="list-style-type: none"> ・緩和ケアや医療用麻薬についてのパスを作ったが、作るところまではよいが運用が進まない

カテゴリーに相当する代表的な項目を示す

連携している」、「病院から医師や看護師が在宅を行う診療所や訪問看護ステーションの立ち上げを行い軌道に乗ったら地域で雇った職員に渡す」、「訪問看護ステーションは休日がないので）人手が足りない時は病院看護師と交代する」などといった取り組みがあげられたが、実績や質に合わせた診療報酬上の評価などの対応がないと解決は難しいとの意見が多かった。また、【療養場所の不足】についても、緩和ケア病棟だけの問題ではなく、地域全体の療養場所の不足・偏在、機能に応じて適切な利用がされていないという観点から語られた。

III. 考 察

本研究では、いくつかの注目に値する地域緩和ケアの普及のための工夫が認められた。

一つには、【すでにあるものを利用する】ことである。現在、がん診療連携拠点病院の役割として、医療者対象の研修会や市民対象の講演会をそれぞれ行うことが求められているが⁴⁾、実際に、研修会や講演会を新しく講習会を企画・実施することは必ずしも効率的でない⁵⁾と今回の研究対象は考えていた。元来施設内で行われている研修会を地域に公開することや、患者会をサポートする形や市民イベントへの参加など、もともとある仕組みを上手に利用できる位置付けが必要な可能性があると考えられる。

二つには、教育の方法として講義のみならずグループワーク、事例検討、実習など様々な方策がとられていた。一般的に教育方法としては一方向的な講義よりも双方向的な手段が有効であるが、地域緩和ケアではグループワークがより有効と体験されることや、職種やテーマによって体験する有用性が異なることが示唆されている^{6,7)}。どのような対象にどのような教育方法がよいのかについて、各地域での知見を系統的に収集することによって、最も効果的な教育方法を明らかにすることが求められていると考えられる。

三つには、【診療所医師のアシストをする訪問看護師や保険薬局薬剤師を対象とする】方策は注目し得る。診療所の医師はすべての疾患の患者を診察するため、年間に診療するがん患者は必ずしも多くないが、訪問看護ステーションではがん患者の診療経験が平均して多い⁸⁾。地域では診療所、訪問看護ステーション、保険薬局などが一定の単位として機能する機会が多く、職種ごと（特に診療所医師）にプログラムを提供するのではなく、訪問看護師と保険薬局と診療所医師を一つのチームとしてがん緩和ケアの知識や技術を提供するプログラムを検討する価値があると考えられる。

四つには、多彩な啓発活動が行われている割には効果が実感されていないことである。これまでに、この数年で全国調査でも緩和ケアに関する認識にはあまり変化は

みられないこと⁴⁾、講演会によって一時的に緩和ケアの認識は変化するが時間経過とともに元に戻ること^{9,10)}、緩和ケアに関する冊子などは広く配布するより、対象となる患者の多いところでより効率的に配布されることが確認されている¹¹⁾。緩和ケアに関する啓発については、広く薄く行う活動よりも、臨床のなかで体験を蓄積することや、対象患者に絞った対応など活動の評価と方針の見直しが必要なのかもしれない。

五つには、がん専門病院においても退院支援など地域連携の取り組みが積極的に行われていることである。取り組みは、①臨床活動としては退院前カンファレンスと外来での在宅支援の充実、②教育活動としては病院内での医師・看護師への在宅の視点についての教育、③地域連携のネットワーク作りの三つに分けられた。特に、外来での在宅支援について人員や体制の増員などが必要になることが示唆される。また工夫として、有効な教育のためには病院看護師が訪問看護ステーションなど在宅医療の現場を体験することと、在宅がカリキュラムに入っていない時期に教育を受けた可能性の高い師長クラスに対する教育の重要性が述べられた。これらの地域連携の取り組みについては、現在定まった方法は提示されておらず、各施設の取り組み方を系統的に蓄積することが重要であると考えられる。

六つには、課題としてあげられたものはがん緩和医療に限らないことがほとんどであったことである。療養場所の確保、在宅診療を行う主治医（かかりつけ医師）機能、経済的問題、個人情報と患者情報のチームでの共有などが緩和医療にかかわらない問題であり、がん医療を越えた枠組みでの議論が必要であることが示唆される。

本研究の限界として、限られた施設のフォーカスグループによる意見なので一般化はできない。

結 論

地域の緩和ケアの知識の普及、患者・家族・住民への啓発、専門的な緩和ケアの提供、緩和ケアの連携の促進に取り組む上での工夫が施設ごとに行われており、本研究で作成されたリストをみることで各活動を行う上での工夫を系統的に整理することに役立つと考えられる。さらに、同様のフォーカスグループを全国的に行いその結

果を迅速に公開する仕組みを作ることは、全国水準での地域緩和ケアの課題や改善のための工夫を共有することを通じて、わが国の地域緩和ケアの向上に貢献する可能性がある。

謝辞 本研究は、厚生労働科学研究費補助金 第3次対がん総合戦略研究事業「緩和ケアプログラムによる地域介入研究」の助成を受けた。調査実施に当たり、ご協力いただいた国立がん研究センター東病院・臨床開発センター・精神腫瘍学開発部の丹下亜土さん、林響子さんに心よりお礼申し上げます。

文 献

- 1) Miyashita M, Sanjo M, Morita T, *et al*: Good death in cancer care: a nationwide quantitative study. *Ann Oncol* 18(6):1090-1097, 2007.
- 2) Yamagishi A, Morita T, Miyashita M, *et al*: Preferred place of care and place of death of the general public and cancer patients in Japan. *Support Care Cancer* 2012 Jan 24. [Epub ahead of print]
- 3) 下山直人, 森田達也: わが国の緩和ケアの現状とこれからの行動計画 Ver. 1. 厚生労働科学研究費補助金(がん臨床研究事業)「緩和ケアのガイドライン作成に関するシステム構築に関する研究」, 主任研究者: 下山直人「緩和ケアのグランドデザイン作成に関する研究」, 分担研究者: 森田達也, 2007.
- 4) 加藤雅志: II. がん対策基本法後にホスピス緩和ケアはどう変わったか—成果と残された課題—. (財)日本ホスピス・緩和ケア研究振興財団「ホスピス緩和ケア白書」編集委員会・編, ホスピス緩和ケア白書 2011, 2011, pp6-12.
- 5) 山岸暁美, 森田達也, 古村和恵・他: 地域のがん緩和ケアの課題と解決策の抽出—OPTIM-Studyによる複数地域・多職種による評価—. *癌と化学療法* 38(11):1889-1895, 2011.
- 6) 鄭 陽, 井村千鶴, 野末よし子・他: 地域における講義とグループディスカッションを複合した多職種セミナーの有用性. *ペインクリニック* 30(11):1553-1563, 2009.
- 7) 末田千恵, 山岸暁美, 鈴木 聡・他: どのような緩和ケアセミナーが求められているか: 4,188名が評価した緩和ケアセミナーの有用性に影響する要因. *ペインクリニック* 32(8):1215-1222, 2011.
- 8) Yamagishi A, Morita T, Miyashita M, *et al*: Providing palliative care for cancer patients: The views and exposure of community general practitioners and district nurses in Japan. *J Pain Symptom Manage* 2011 Jun 22. [Epub ahead of print]
- 9) 古村和恵, 山岸暁美, 赤澤輝和・他: 市民の緩和ケアに対するイメージの変化. *緩和ケア*: in press.
- 10) Sato K, Miyashita M, Morita T, *et al*: The long-term effect of a population-based educational intervention focusing on end-of-life home care, life-prolongation treatment, and knowledge about palliative care. *J Palliat Care* 25(3):206-212, 2009.
- 11) 赤澤輝和, 川崎由実, 山田博英・他: 緩和ケアの啓発用冊子を病院内のどこに置いたらよいか? *緩和ケア* 21(2):221-225, 2011.

短報

遺族調査に基づく自宅死亡を希望していると推定されるがん患者数

森田 達也¹⁾, 宮下 光令²⁾, 井上芙蓉子³⁾, 佐藤 一樹²⁾,
五十嵐 歩⁴⁾, 五十嵐美幸⁵⁾, 山口 拓洋⁶⁾, 橋本 修二⁷⁾

1) 聖隷三方原病院 緩和と支持治療科, 2) 東北大学大学院 医学系研究科 保健学専攻 緩和ケア看護学分野, 3) 東北大学病院, 4) 東京医科歯科大学大学院 保健衛生学研究科 高齢者看護・ケアシステム開発学分野, 5) 東北大学大学院 医学系研究科 保健学専攻 老年保健看護学分野, 6) 東北大学大学院 医学系研究科 医学専攻 医学統計学分野, 7) 藤田保健衛生大学 医学部 衛生学講座

受付日 2012年7月10日 / 改訂日 2012年7月30日 / 受理日 2012年8月2日

本研究の目的は、全国4地域を対象とした緩和ケアの普及に関する地域介入研究で取得された実際の死亡場所と死亡数、遺族調査のデータをもとに、自宅死亡を希望していると考えられるがん患者数の推定を行うことである。死亡場所・死亡数のデータは人口動態統計などの資料から収集した。遺族調査は全国4地域52施設の遺族1,137名を対象として実施された。「自宅死亡の希望推定数」を、自宅死亡した患者で遺族が患者はそれを望んでいたと推測した数、および一般病棟・緩和ケア病棟で死亡した患者で、遺族が患者は自宅で死亡することを望んでいたと推測した数から求めた。自宅死亡の希望推定数は、対象地域ではがん死亡の32.8% [95%信頼区間: 31.7, 33.9] であり、全国数値に基づくと11.1万人(がん死亡の31.2% [95%信頼区間: 31.1, 31.4])であった。

Palliat Care Res 2012; 7(2): 403-7

Key words: 自宅死亡, 緩和ケア, がん

背景・目的

がん患者にとって、望んだ場所で療養生活を送ることは最も重要な希望の一つである^{1,2)}。一般市民やがん患者を対象とした調査では、がん患者の約50%が自宅を希望する療養場所や死亡場所として望んでいることが示唆されているが、実際の自宅死亡率は2010年で7.8%であり、患者が自宅で過ごす体制の整備が求められている³⁻⁶⁾。

自宅死亡率がどの程度であれば患者の希望が満たされるかを推定することは、求められる患者数に応じた医療計画を設定するために重要である。しかし、療養場所の希望は患者の状態によって変わるため、一般市民や状態の良いがん患者を対象とした調査から見積もられる希望は実際の希望と必ずしも一致しない^{7,8)}。一方、代理評価や想起バイアスによる限界があるものの、遺族調査により療養場所の希望が実際に達成されたかを評価することは国際的にしばしば行われる方法である^{9,10)}。これまでにわが国で行われた遺族調査では、対象が緩和ケア病棟の遺族に限られており、自宅死亡を望む患者数を推定することはできなかった¹¹⁻¹³⁾。

本研究の目的は、地域介入研究で行われた地域全体の遺族調査をもとにして、自宅死亡を希望しているがん患者数の推定を行うことである。

対象・方法

本研究は、OPTIMプロジェクト(Outreach Palliative care Trial of Integrated regional Model, 厚生労働科学研究費補助金第3次対がん総合戦略研究事業「緩和ケアプログラムによる地域介入研究」)の一部として行われたものである^{14,15)}。OPTIMプロジェクトは、4地域(鶴岡地域、柏地域、浜松地域、長崎地域)を対象とした地域介入による前後比較研究である。主要評価項目は、quality of care, 専門緩和ケアサービスの利用数、自宅死亡率であり、地域に対する介入として複合介入が行われた。

研究の倫理的・科学的妥当性は、本研究のために設置された倫理委員会および参加施設の倫理委員会の承認を得た。本研究では、取得された数値のうち、死亡場所・死亡数、遺族調査のデータの一部を利用した。

調査方法

① 死亡場所と死亡数

4地域を対象として、2010年のがん死亡総数、自宅死亡数、病院・診療所での死亡数を人口動態統計から取得した。4地域に存在するすべてのホスピス・緩和ケア病棟(4つの都道府県認可の緩和ケア病棟と1つの認可を受けていない緩和ケア病棟)の2010年の死亡数を各施設から取得し、「緩和ケア病棟死亡数」として、人口動態統計から取得した病院・診療所での死

Corresponding author: 森田達也 | 聖隷三方原病院 緩和と支持治療科
〒433-8558 静岡県浜松市北区三方原町3453
TEL 053-436-1251 FAX 053-438-2971 E-mail: tmorita@sis.scirci.or.jp

表1 遺族調査による死亡場所ごとの「望んだ場所で最期を迎えられた」「自宅を希望していた」割合

死亡場所	「望んだ場所で最期を迎えられた」			
	「まったくそう思わない」「そう思わない」「ややそう思わない」	「どちらともいえない」	「ややそう思う」「そう思う」「とてもそう思う」	「自宅を希望していた」
一般病院 (n=668)	241 36.1% [32.4, 39.9]	161 24.1% [20.9, 27.4]	244 36.5% [32.9, 40.3]	182 27.3% [23.9, 30.8]
緩和ケア病棟 (n=248)	70 28.2% [22.7, 34.3]	48 19.4% [14.6, 24.8]	127 51.2% [44.8, 57.6]	57 23.0% [17.9, 28.7]
自宅 (n=221)	4 1.8% [0.5, 4.6]	4 1.8% [0.5, 4.6]	204 92.3% [88.0, 95.5]	—

%は母数を死亡場所とした割合と95%信頼区間を示す。太字は、自宅死亡の希望推定数の算出に用いる数値を示す。

亡数から、緩和ケア病棟死亡数を引いたものを「一般病棟死亡数」とした。

次に、全国の2010年のがん死亡総数、自宅死亡数、病院・診療所での死亡数を人口動態統計から取得した。全国の都道府県認可を受けたホスピス・緩和ケア病棟の2010年の死亡数を日本ホスピス緩和ケア協会の統計から取得し、「緩和ケア病棟死亡数」とした。人口動態統計から取得した病院・診療所での死亡数から、緩和ケア病棟死亡数を引いたものを「一般病棟死亡数」とした。

② 遺族調査

地域のがん患者の遺族を病院、診療所の死亡者から同定した。病院については、各地域に存在する病院54病院のうち精神科病院、リハビリテーション病院、療養型病院など20病院を除外し、がん患者を診療していると考えられる34病院を対象施設とした。そのうち、21病院(鶴岡4病院、柏6病院、浜松6病院、長崎5病院)が調査に参加した。診療所については、がん患者の在宅診療を行っていると考えられる診療所を地域の医療情報から同定し、参加を依頼した。病院・診療所合わせて、52施設が対象となった。調査対象となった病院の病床数は対象病院の81%(8,964/11,033床)、がん患者の死亡数総数に占める調査対象となった死亡数の割合は40%(2,212/5,546)であった。

調査対象施設で、または調査対象施設で診療を受けて自宅で死亡したがん患者の遺族を対象として、郵送法による質問紙調査を行った。

遺族の適格基準は、①死亡時20歳以上のがん患者の遺族で、遺族の年齢が20歳以上、②原発が肺、胃・食道、肝臓・胆嚢・膵臓、大腸・直腸、乳腺、腎臓・前立腺・膀胱、子宮・卵巣のいずれか、③2010年4月1日～2011年3月31日に患者が死亡したもの、④居住地が調査対象地域、⑤遺族にがんの病名告知がされている、⑥入院・訪問診療の開始から死亡までの期間が3日以上、である。

除外基準は、①遺族が同定できない・いない、②認知症、精神疾患の理由のため質問紙を理解できないと考えられる、③調査に回答することが遺族の精神的苦痛が大きいと担当医が判断したもの、④死亡原因が治療関連死、がんと関連しない合併症によるもの、⑤死亡場所が集中治療室、⑥主治医が異動・不在のため調査可否の判断ができない、とした。

調査項目は、Care Evaluation Scale、Good Death Inventoryなどであった¹⁴⁾。Good Death Inventoryの項目に「望んだ場所で最期を迎えられた」という設問を含み、「とてもそう思う」「そう思

う」「ややそう思う」「どちらともいえない」「ややそう思わない」「そう思わない」「まったくそう思わない」の7件法で回答を求めた¹⁶⁾。また、「まったくそう思わない」「そう思わない」「ややそう思わない」と回答した遺族に対して、遺族の推定による望んでいた死亡場所を「病院」「ホスピス・緩和ケア病棟」「自宅」「その他」のいずれかで尋ねた。

解析

最初に、遺族調査をもとに、病院死亡、緩和ケア病棟死亡、自宅死亡ごとに、Good Death Inventoryの「望んだ場所で最期を迎えられた」という項目に対する回答の分布、「望んだ場所で最期を迎えられた」と回答しなかった一般病棟、緩和ケア病棟の遺族の、遺族の推測による望んでいた死亡場所として自宅と回答したものの割合、95%信頼区間を算出した。

次に、「自宅死亡の希望推定数」を以下の3つの合計として求めた。①(人口動態統計から取得された自宅死亡数)×(遺族調査により自宅で死亡した遺族が「望んだ場所で最期を迎えられた」に「ややそう思う」「そう思う」「とてもそう思う」と回答した割合)、②(一般病棟死亡数)×(遺族調査により一般病棟で死亡した遺族が「望んだ場所で最期を迎えられた」に「ややそう思わない」「そう思わない」「とてもそう思わない」と回答したもののうち、望む死亡場所として「自宅」を挙げた割合)、③(緩和ケア病棟死亡数)×(遺族調査により緩和ケア病棟で死亡した遺族が「望んだ場所で最期を迎えられた」に「ややそう思わない」「そう思わない」「とてもそう思わない」と回答したもののうち、望む死亡場所として「自宅」を挙げた割合)。

結果

適格基準を満たした遺族2,212名のうち436名が除外基準に該当し、1,776名に発送された。あて先不明が48名、回答拒否が82名であり、1,137名から回答を得た(有効回収率66%)。

一般病院で死亡した患者の遺族668名のうち36.1%が「望んだ場所で最期を迎えられた」に「ややそう思わない」「そう思わない」「まったくそう思わない」と回答し、182名(全体の27.2%)が自宅を希望していた死亡場所として挙げた(表1)。緩和ケア病棟で死亡した患者の遺族248名のうち28.2%が「望んだ場所で最期を迎えられた」に「ややそう思わない」「そう思わない」「まったくそう思わない」と回答し、57名(全