

Palliative care needs of cancer outpatients receiving chemotherapy: an audit of a clinical screening project

Tatsuya Morita · Koji Fujimoto · Miki Namba ·
Naoko Sasaki · Tomoko Ito · Chika Yamada ·
Arisa Ohba · Motoki Hiroyoshi · Hiroshi Niwa ·
Takeshi Yamada · Tsuneo Noda

Received: 11 December 2006 / Accepted: 3 May 2007 / Published online: 5 July 2007
© Springer-Verlag 2007

Abstract

Purpose Although more and more cancer patients are receiving chemotherapy in outpatient settings in their

advanced stage and could have a broad range of palliative care needs, referral to the specialized palliative care service is often delayed. The primary aim of this study is to explore the usefulness of a combined intervention for cancer patients in identifying patients with underrecognized palliative care needs and referring them to the specialized palliative care service. The intervention consisted of (1) introducing the specialized palliative care service when starting chemotherapy, (2) using screening tools, and (3) providing on-demand specialized palliative care service.

T. Morita (✉)

Department of Palliative and Supportive Care, Palliative Care Team and Seirei Hospice, Seirei Mikatahara Hospital, 3453 Mikatabara-cho, Hamamatsu, Shizuoka 433-8558, Japan
e-mail: tmorita@sis.seirei.or.jp

K. Fujimoto · M. Namba

Palliative Care Team, Seirei Mikatahara General Hospital, 3453 Mikatahara-cho, Hamamatsu, Shizuoka 433-8558, Japan

N. Sasaki · T. Ito · C. Yamada · A. Ohba

Pharmacology Department, Seirei Mikatahara General Hospital, 3453 Mikatahara-cho, Hamamatsu, Shizuoka 433-8558, Japan

M. Hiroyoshi

Department of Surgery, Seirei Mikatahara General Hospital, 3453 Mikatahara-cho, Hamamatsu, Shizuoka 433-8558, Japan

H. Niwa · T. Yamada

Department of Thoracic Surgery, Seirei Mikatahara General Hospital, 3453 Mikatahara-cho, Hamamatsu, Shizuoka 433-8558, Japan

T. Noda

Department of Gynecology, Seirei Mikatahara General Hospital, 3453 Mikatahara-cho, Hamamatsu, Shizuoka 433-8558, Japan

Materials and methods All cancer patients newly starting chemotherapy with primary tumor sites of the lung, gastrointestinal, pancreas, bile duct, breast, ovary, and uterus were included. As routine practice, at the first instruction about chemotherapy, pharmacists provided information about the role of the specialized palliative care service using a pamphlet and handed out screening questionnaires. Screening questionnaires were distributed at every hospital visit. Treating physicians and/or nurses checked the questionnaire before examining the patients. The patients were referred to the palliative care team, if (1) the patients voluntarily wished for the specialized palliative care service or (2) the treating physicians clinically determined that, on the basis of the screening results, the patients had physical or psychological needs appropriate for referral to the specialized palliative care service. The screening questionnaire included an open-ended question about their greatest concerns, the severity of 11 physical symptoms, overall quality-of-life, the distress thermometer, help for information about the treatment and decision-making, economic problems, nutri-

tion, daily activities, and wish for help from the specialized palliative care service.

Results Of 211 patients who newly started chemotherapy, 5 patients refused to complete the questionnaire (compliance rate, 98%). We obtained 1,000 questionnaires from 206 patients. The percentages of missing values ranged from 2.7% to 7.0%. Of 206 patients, 38 (18%) were referred to the palliative care team due to newly recognized problems, in addition to 10 patients with problems well-recognized by primary physicians. The total percentage of patients receiving specialized palliative care service was thus 23% of all patients. Frequently identified problems were oral problems (20%), insomnia (20%), help with information and decision-making (16%), psychological distress defined as the distress thermometer (14%), severe fatigue (9.0%), and severe appetite loss (8.8%). As a whole, problems were identified in half of all questionnaires.

Conclusion The combined intervention of introducing the specialized palliative care service, using screening tools and providing on-demand specialized palliative care service, was feasible as part of the routine clinical practice for all cancer patients starting chemotherapy. It might be useful in identifying patients with underrecognized palliative care needs and referring them to the specialized palliative care service at the appropriate time.

Keywords Palliative care team · Neoplasms · Screening · Chemotherapy head · Outpatient

Introduction

The recent literature indicates that more and more cancer patients receive chemotherapy in outpatient settings in their advanced stage [1]. They have a broad range of palliative care needs including physical symptoms, psychological distress, help with decision-making, and economical and practical support [2–7]. Conceptually, palliative care can and should be provided for all patients along with disease-modifying treatment [8]. Referral to the specialized palliative care service is, however, often delayed because patients regard receiving palliative care as an *alternative*, not an additional, resource of anticancer treatment [9–11]. Introducing the specialized palliative care service as an additional resource to improve the quality-of-life of all patients at the earlier stage of cancer treatment, focusing on patient distress not on the stage of the disease, can be a

useful strategy to provide adequate palliative care [12]. Several intervention trials have suggested that the routine use and feedback to the treating physicians of quality-of-life measurements or symptom assessment scales could contribute to improving physician recognition of patient quality-of-life aspects with some beneficial effects on patient psychological well-being [13–17]. On the other hand, some clinical trials including more intensive interventions, such as cognitive behavior intervention with systematic identification of patient needs, have demonstrated positive outcomes in patient physical well-being, not only psychological issues [18–22]. In addition, multidisciplinary intervention by specialized palliative care teams in outpatient settings could contribute to enhancing patient quality-of-life [23–26]. These findings suggest that a combined intervention of (1) introducing the specialized palliative care service at the earlier stage of disease trajectory, (2) using screening tools, and (3) providing on-demand specialized palliative care might contribute to a better quality-of-life for cancer patients receiving active anticancer treatment.

The primary aim of this project is to explore the usefulness of such intervention in identifying patients with underrecognized palliative care needs and referring them to the specialized palliative care service. An additional aim was to clarify the prevalence of physical and psychological symptoms and concerns among a heterogeneous sample of cancer patients receiving outpatient chemotherapy in a regional cancer center.

Materials and methods

This brief descriptive study included all cancer patients newly starting chemotherapy with primary tumor sites of the lung, gastrointestinal, pancreas, bile duct, breast, ovary, and uterus from April to October 2006. We had decided to include the patients receiving adjuvant chemotherapy because they might receive some benefit from professional emotional support by a member of the palliative care team (the leading department of this project is the Department of Palliative and Supportive Care). As part of the routine practice, at the first instruction about chemotherapy, pharmacists provided information about the role of the specialized palliative care service using a pamphlet and handed out screening questionnaires with coaching on how to complete them. Screening questionnaires were thereafter distributed at every hospital visit. If the patients refused to complete

the questionnaire or recognized no need, they were not obliged to complete the questionnaire.

Treating physicians and/or nurses checked the screening questionnaire before examining the patients. The patients were referred to the palliative care team, if (1) the patients voluntarily wished for the specialized palliative care service or (2) the treating physicians determined that, on the basis of the screening results, the patients had physical or psychological needs appropriate for referral to the specialized palliative care service. Although we instructed the physicians to consider the scores of 5 or more as a threshold for the screening, the decision whether the treating physicians referred patients to the palliative care team was clinically made due to no established cutoff points. In addition, a research nurse provided brief feedback about the screening results via the electronic medical recording system.

Palliative care team activity is widespread throughout our hospital and could respond to all consultations within a few days [27, 28].

Screening questionnaire

The study group constructed the screening questionnaire on the basis of existing validated instruments [29–33]. As the primary intention of this activity was to identify patients with underrecognized needs and facilitate their referral to the specialized palliative care service within the routine clinical practice, not to clarify the exact prevalence of each need, we decided to make the questionnaire as simple and short as possible.

The screening questionnaire included (1) an open-ended question about the greatest concerns of patients; (2) 0–10 numeric rating scales of 8 physical symptoms (pain, dyspnea, nausea, appetite loss, somnolence, fatigue, constipation/diarrhea, numbness) adopted from the Japanese version of the M.D. Anderson Symptom Inventory (MDASI) after modification of the interval (24 h to 1 week) and the timing (worst to average severity) [29]; (3) presence or absence of oral problems, fever, and insomnia; (4) 0–7 numeric rating scale of overall quality-of-life adopted from item 29 of the EORTC-C30 [30]; (5) the distress thermometer [31, 32]; (6) presence or absence of help in 4 areas, i.e., information about the treatment and decision-making, economic problems, nutrition, and daily activities [33]; and (7) wish for help of the specialized palliative care service (see Appendix).

Our hospital required no Institutional Review Board approval for the retrospective analysis of clinical activity,

but admitted patients gave written consent that their clinical information could be used for clinical research.

Analyses

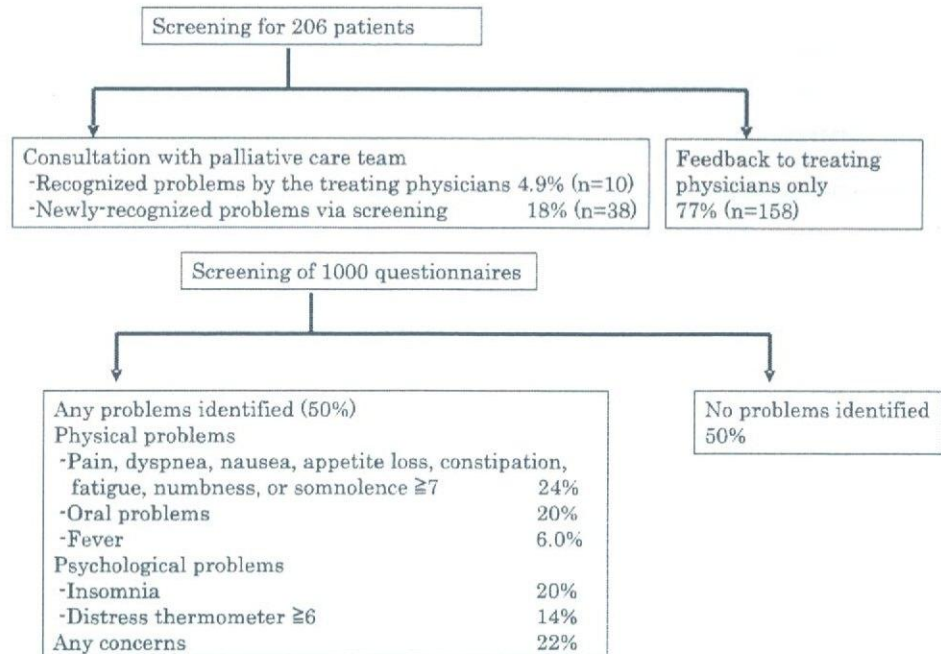
The primary endpoint was the number of patients referred to the palliative care team after treating physicians and/or nurses recognized patient needs via the screening questionnaire.

As additional endpoints, the prevalence of problems was calculated for each visit. For calculations, we adopted ad hoc definition of moderate and severe symptom intensities for the MDASI items as 4–6 and 7–10, respectively. We used cutoff points on the distress thermometer of 6 or more following the previous findings [31, 32]. We determined that a patient had problems if he/she had either MDASI symptoms of 7 or more, oral problem, fever, insomnia, distress thermometer of 6 or more or any help with

Table 1 Patient backgrounds (*n*=206)

Summary of patient backgrounds	
Age	62±11 years
Sex	
Male	41% (<i>n</i> =84)
Female	59% (<i>n</i> =122)
Primary sites	
Lung	30% (<i>n</i> =62)
Breast	27% (<i>n</i> =56)
Colon, rectum	15% (<i>n</i> =31)
Stomach	13% (<i>n</i> =26)
Uterus, ovary	10% (<i>n</i> =21)
Pancreas, bile duct	2.9% (<i>n</i> =6)
Others	3.9% (<i>n</i> =8)
Chemotherapy regimens	
Taxanes	27% (<i>n</i> =55)
Carboplatin and taxanes	19% (<i>n</i> =39)
Doxorubicin and cyclophosphamide	12% (<i>n</i> =25)
Oral tegafur gimeracil oteracil	11% (<i>n</i> =22)
Fluorouracil	10% (<i>n</i> =21)
Gemcitabin	3.4% (<i>n</i> =7)
Irinotecan with/without taxanes	2.9% (<i>n</i> =6)
Transtumab with/without taxanes	2.9% (<i>n</i> =6)
Cyclophosphamide, methotrexate, and fluorouracil	2.4% (<i>n</i> =5)
Gefetinib	1.5% (<i>n</i> =3)
Low-dose cisplatin and 5-fluorouracil	1.5% (<i>n</i> =3)
Vinorelbine	1.0% (<i>n</i> =2)
Oxaliplatin and 5-fluorouracil/leucovorin	1.0% (<i>n</i> =2)
Oral capecitabine	1.0% (<i>n</i> =2)
Others	3.4% (<i>n</i> =7)

Fig. 1 Results



information and decision-making, nutrition, economic problems or daily activities.

Results

During this study interval, of 211 patients who newly started chemotherapy, 5 patients refused to complete the screening questionnaire (compliance rate, 98%). Each patient completed a median of 3.0 screening questionnaires during this study period (range 0–15) and we obtained 1,000 questionnaires from 206 patients. The percentages of missing values ranged from 2.7% (appetite loss) to 7.0% (distress thermometer). Table 1 summarizes the patient backgrounds.

Of 206 patients who completed the initial questionnaire, 38 (18%) were referred to the palliative care team due to newly recognized problems via the screening tool, in addition to 10 patients who consulted the palliative care team due to well-recognized problems (Fig. 1). The percentage of patients receiving the specialized palliative care service was thus 23% of all patients by treating physicians (48/206).

The main reasons for the referral via the screening tool were: psychological distress (58% of 38 patients, $n=22$), appetite loss/nausea/constipation (26%, $n=10$), pain (24%,

$n=9$), numbness (13%, $n=5$), fatigue (13%, $n=5$), and dyspnea/cough (5.3%, $n=2$). On the other hand, the main symptoms of the patients who consulted the palliative care team due to well-recognized problems were: pain (40% of 10 patients, $n=4$), dyspnea (30%, $n=3$), delirium (20%, $n=2$), and psychological distress (10%, $n=1$).

For the questionnaire level (Table 2), frequently identified problems were oral problems (20%), insomnia (20%), help with information and decision-making (16%), psychological distress (defined as the distress thermometer ≥ 6 ; 14%), severe fatigue (9.0%), and severe appetite loss (8.8%). As a whole, problems were identified in half of all questionnaires (Fig. 1).

Discussion

The first important finding of this study was the feasibility of our clinical intervention. The percentage of patients who completed the screening questionnaire at instruction was over 90%. The percentages of missing values in each screening item were below 7.0%. These findings demonstrated that this intervention was feasible for the majority of cancer patients receiving chemotherapy as part of the routine clinical practice.

The second important finding was the potential usefulness of our intervention in identifying patients with under-

Table 2 Problems identified in 1,000 questionnaires

	Prevalence (%) ^a			Mean±SD (median) ^b
	Severe	Moderate	Total	
Physical problems				
MDASI items				
Fatigue	9.0	16	25	2.4±2.5 (2.0)
Appetite loss	8.8	11	20	1.9±2.6 (0.0)
Constipation	5.6	13	19	1.7±2.3 (1.0)
Somnolence	4.9	14	19	1.8±2.2 (1.0)
Pain	4.9	9.9	15	1.6±2.1 (1.0)
Numbness	6.0	7.5	14	1.4±2.3 (0.0)
Dyspnea	2.9	7.5	11	1.2±1.9 (0.0)
Nausea	3.4	6.9	10	1.1±2.0 (0.0)
Oral problems			20	
Fever			6.0	
Psychological problems				
Insomnia			20	
Distress thermometer			14	
Concern				
Information and help with decision-making			16	
Nutrition			6.8	
Daily activities			5.6	
Economic problems			2.9	

^a The percentages of responses with moderate (4–6) and severe (7–10) symptom intensity for the MDASI items. The percentages of the score ≥ 6 for the distress thermometer. The percentages of problem presence for the other items.

^b Mean values calculated for the MDASI items only.

recognized palliative care needs and referring them to the specialized palliative care service when patients wished for. Among the half of the patients who received chemotherapy and reported physical or psychological problems or concerns at the questionnaire level, 23% of all cancer patients were newly referred to the palliative care team with the primary aim of improving their quality-of-life. Despite clear limitation of the lack of control group, this finding strongly indicates that our intervention could provide specialized care for patients with profound symptoms irrespective of the disease extent.

The additional but third important finding was the clarification of the types of symptoms and concerns observed

in heterogeneous cancer outpatients receiving chemotherapy. In this study, psychological issues (insomnia, distress), concern about information and decision-making, nutrition-related issues (oral problems and appetite loss), and fatigue were major concerns for patients. Consistent with the previous findings from Western countries, this finding indicates that developing systematic intervention strategies targeting psychosocial distress, decision-making, nutrition, and fatigue is of great importance and an emerging task for Japanese palliative care specialists [34–39].

In addition, this study revealed a considerable difference between the symptom patterns of the patients referred via the screening system and those from the treating physicians. While pain, dyspnea, and delirium were major reasons for the referral from the treating physicians, the screening system identified a broader range of patient distress, such as psychological distress, appetite loss, numbness, and fatigue. The result indicates that the screening system could be useful in identifying the patients with serious psychological distress, appetite loss, numbness, and fatigue, which are often overlooked by physicians.

This was a descriptive study of routine clinical experience and thus had considerable limitations. First, we did not formally measure the changes in the symptoms and concerns after consulting the palliative care team and we cannot conclude whether referral to the specialized palliative care service actually provided a benefit for the patients. Second, as the patients were a heterogeneous sample of their primary tumor sites, stages, and chemotherapy regimens, the results might not be automatically generalized to specific target populations. We believe this is not a fatal flaw of this study because we need to develop a useful system for heterogeneous outpatients receiving chemotherapy. Third, as this was a single institution study where the palliative care unit and palliative care team have been regarded as an essential function of the hospital [27, 28], the results could not be generalized to other institutions. Finally, because we had not decided to explore solid cutoff points, the most appropriate cutoff points for the screening and the definition of moderate and severe symptom intensities should be further studied.

In conclusion, the combined intervention of introducing the specialized palliative care service, using screening tools, and providing on-demand specialized palliative care service when starting chemotherapy as a part of routine clinical practice was feasible and could be useful in identifying patients with underrecognized palliative care needs and referring them to specialized palliative care service. To evaluate the accurate effects of this intervention, controlled trial is promising.

Appendix

Screening questionnaire

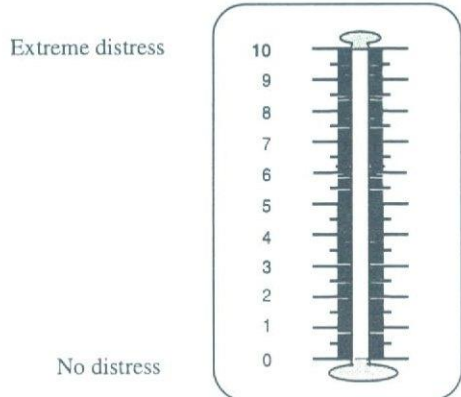
A. What is your greatest concern?

B. Physical symptoms. During the last week, how severe were your symptoms on the average?

	Not present ←————→ As bad as you can imagine										
	0	1	2	3	4	5	6	7	8	9	10
Pain	0	1	2	3	4	5	6	7	8	9	10
Shortness of breath	0	1	2	3	4	5	6	7	8	9	10
Nausea	0	1	2	3	4	5	6	7	8	9	10
Lack of appetite	0	1	2	3	4	5	6	7	8	9	10
Drowsy (sleepy)	0	1	2	3	4	5	6	7	8	9	10
Fatigue (tiredness)	0	1	2	3	4	5	6	7	8	9	10
Constipation/Diarrhea	0	1	2	3	4	5	6	7	8	9	10
Numbness or tingling	0	1	2	3	4	5	6	7	8	9	10
Oral problems	YES	NO	Fever	YES	NO	Sleep Difficulty	YES	NO			

C. In the past week...

- | | Very poor ←————→ Excellent | | | | | | | |
|----------------------------|----------------------------|---|----|---|---|---|---|---|
| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 1) Overall quality of life | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 2) Body Weight | (|) | kg | | | | | |
| 3) How distressed are you? | | | | | | | | |



D. Do you need some help with...

- Information about the treatment and help with decision making
- Economic problems
- Nutrition
- Daily activities (house work, work, toilet...)

E. Do you wish for specialized palliative care (see the reverse side for detailed information)

→
 WISH NOT wish

References

- Earle CC, Neville BA, Landrum MB, Ayanian JZ, Block SD, Weeks JC (2004) Trends in the aggressiveness of cancer care near the end of life. *J Clin Oncol* 22:315–321
- Bang SM, Park SH, Kang HG et al (2005) Changes in quality of life during palliative chemotherapy for solid cancer. *Support Care Cancer* 13:515–521
- Munkres A, Oberst MT, Hughes SH (1992) Appraisal of illness, symptom distress, self-care burden and mood states in patients receiving chemotherapy for initial and recurrent cancer. *Oncol Nurs Forum* 19:1201–1209
- Matsuyama R, Reddy S, Smith TJ (2006) Why do patients choose chemotherapy near the end of life? A review of the perspective of those facing death from cancer. *J Clin Oncol* 24:3490–3496
- Schonwetter RS, Roscoe LA, Nwosu M, Zilka B, Kim S (2006) Quality of life and symptom control in hospice patients with cancer receiving chemotherapy. *J Palliat Med* 9:638–645
- Whitmer KM, Pruemer JM, Nahleh ZA, Jazieh AR (2006) Symptom management needs of oncology outpatients. *J Palliat Med* 9:628–630
- Newell S, Sanson-Fisher RW, Girgis A, Ackland S (1999) The physical and psycho-social experiences of patients attending an outpatient medical oncology department: a cross-sectional study. *Eur J Cancer Care* 8:69–72
- World Health Organization (2002) National cancer control programmes. Policies and managerial guidelines, 2nd edn. WHO, Geneva
- Christakis NA, Escarce JJ (1996) Survival of medicare patients after enrollment in hospice programs. *N Engl J Med* 335:172–178
- Costantini M, Toscani F, Gallucci M et al (1999) Terminal cancer patients and timing of referral to palliative care: a multicenter prospective cohort study. *J Pain Symptom Manage* 18:243–252
- Morita T, Akechi T, Ikenaga M et al (2005) Late referrals to specialized palliative care service in Japan. *J Clin Oncol* 23:2637–2644
- Bruera E (2006) Process and content of decision making by advanced cancer patients. *J Clin Oncol* 24:1029–1030
- Hoekstra J, de Vos R, van Duijn NP, Schadé E, Bindels PJE (2006) Using the symptom monitor in a randomized controlled trial: the effect on symptom prevalence and severity. *J Pain Symptom Manage* 31:22–30
- Detmar SB, Muller MJ, Schomagel JH, Wever LDV, Aaronson NK (2002) Health-related quality-of-life assessments and patient-physician communication. *JAMA* 288:3027–3034
- Taenzler P, Bultz BD, Carlson LE et al (2000) Impact of computerized quality of life screening on physician behaviour and patient satisfaction in lung cancer outpatients. *Psychooncology* 9:203–213
- Velikova G, Booth L, Smith AB et al (2004) Measuring quality of life in routine oncology practice improves communication and patient well-being: a randomized controlled trial. *J Clin Oncol* 22:714–724
- McLachlan SA, Allenby A, Matthews J et al (2001) Randomized trial of coordinated psychosocial interventions based on patient self-assessments versus standard care to improve the psychosocial functioning of patients with cancer. *J Clin Oncol* 19:4117–4125
- Allen SM, Shah AC, Nezu AM et al (2002) A problem-solving approach to stress reduction among younger women with breast carcinoma. A randomized controlled trial. *Cancer* 94:3089–3100
- Sikorskii A, Given C, Given B, Jeon S, McCorkle R (2006) Testing the effects of treatment complications on a cognitive-behavioral intervention for reducing symptom severity. *J Pain Symptom Manage* 32:129–139
- Miaskowski C, Dodd M, West C (2004) Randomized clinical trial of the effectiveness of a self-care intervention to improve cancer patient management. *J Clin Oncol* 22:1713–1720
- Doorenbos A, Given B, Given C et al (2005) Reducing symptom limitations: effects of a cognitive behavioral intervention randomized trial. *Psychooncology* 14:574–584
- Given C, Given B, Rahbar M et al (2004) Effect of a cognitive behavioral intervention on reducing symptom severity during chemotherapy. *J Clin Oncol* 22:507–516
- Strasser F, Sweeney C, Willey J, Tolley SB, Palmer JL, Bruera E (2004) Impact of a half-day multidisciplinary symptom control and palliative care outpatient clinic in a comprehensive cancer center on recommendations, symptom intensity, and patient satisfaction: a retrospective descriptive study. *J Pain Symptom Manage* 27:481–491
- Bruera E, Michaud M, Vigano A, Neumann CM, Watanabe S, Hanson J (2001) Multidisciplinary symptom control clinic in a cancer center: a retrospective study. *Support Care Cancer* 9:162–168
- Rosenbaum E, Gautier H, Fobair P et al (2004) Cancer supportive care, improving the quality of life for cancer patients. A program evaluation report. *Support Care Cancer* 12:293–301
- Rabow MW, Dibble SL, Pantilat SZ, McPhee SJ (2004) The comprehensive care team. A controlled trial of outpatient palliative medicine consultation. *Arch Intern Med* 164:83–91
- Morita T, Yo T, Fujimoto M (2005) Palliative care team: the first year audit in Japan. *J Pain Symptom Manage* 29:458–465
- Morita T, Imura C, Fujimoto K (2005) Trends toward earlier referrals to a palliative care team. *J Pain Symptom Manage* 30:204–205
- Okuyama T, Wang XS, Akechi T et al (2003) Japanese version of the MD Anderson Symptom Inventory: a validation study. *J Pain Symptom Manage* 26:1093–1104
- Groenvold M, Petersen MA, Aaronson NK et al (2006) The development of the EORTC QLQ-C15-PAL: a shortened questionnaire for cancer patients in palliative care. *Eur J Cancer* 42:55–64
- Akizuki N, Yamawaki S, Akechi T, Nakano T, Uchitomi Y (2005) Development of an impact thermometer for use in combination with the distress thermometer as a brief screening tool for adjustment disorders and/or major depression in cancer patients. *J Pain Symptom Manage* 29:91–99
- Akizuki N, Akechi T, Nakanishi T et al (2003) Development of a brief screening interview for adjustment disorders and major depression in patients with cancer. *Cancer* 97:2605–2613
- Cossich T, Schofield P, McLachlan SA (2004) Validation of the cancer needs questionnaire (CNQ) short-form version in an ambulatory cancer setting. *Qual Life Res* 13:1225–1233
- Koedoot CG, de Haan RJ, Stiggelbout AM et al (2003) Palliative chemotherapy or best supportive care? A prospective study explaining patients' treatment preference and choice. *Br J Cancer* 89:2219–2226
- Grunfeld EA, Maher EJ, Browne S et al (2006) Advanced breast cancer patients' perceptions of decision making for palliative chemotherapy. *J Clin Oncol* 24:1090–1098
- Barsevick AM, Dudley W, Beck S, Sweeney C, Whitmer K, Nail L (2004) A randomized clinical trial of energy conservation for patients with cancer-related fatigue. *Cancer* 100:1302–1310
- Ream E, Richardson A, Dann CA (2006) Supportive intervention for fatigue in patients undergoing chemotherapy: a randomized controlled trial. *J Pain Symptom Manage* 31:148–161
- Jatoi A, Rowland K, Loprinzi CL et al (2004) An eicosapentaenoic acid supplement versus megestrol acetate versus both for patients with cancer-associated wasting: a North Central Cancer Treatment Group and National Cancer Institute of Canada collaborative effort. *J Clin Oncol* 22:2469–2476
- Ravasco P, Grillo IM, Vidal PM, Camilo ME (2005) Dietary counseling improves patients outcomes: a prospective, randomized, controlled trial in colorectal cancer patients undergoing radiotherapy. *J Clin Oncol* 23:1431–1438

Original Article

Screening for Discomfort as the Fifth Vital Sign Using an Electronic Medical Recording System: A Feasibility Study

Tatsuya Morita, MD, Koji Fujimoto, RN, Miki Namba, RN, Emi Kiyohara, RN, Satoshi Takada, BBA, Ritsuko Yamazaki, RN, and Kimiyo Taguchi, RN

Department of Palliative and Supportive Care (T.M.), Palliative Care Team (T.M., K.F., M.N.), and Seirei Hospice (T.M., E.K.), Department of Medical Informatics (S.T.), and Nursing Department (R.Y., K.T.), Seirei Mikatahara Hospital, Shizuoka, Japan

Abstract

Late referral to a specialized palliative care service hinders quality symptomatic management. The aim of this article is to describe the feasibility and clinical usefulness of screening for patient discomfort as the fifth vital sign using an electronic medical recording system to identify patients with undertreated physical symptoms. For the electronic medical recording system, all admitted patients received routine nurse assessment of discomfort (defined as any physical symptom) at every vital signs check using Item 2 of the Support Team Assessment Schedule Japanese version (STAS). All medically treated cancer patients admitted to seven oncology units were automatically screened at one-week intervals. Positive screening was defined as a STAS score of 2 or more at least two times during the previous week. For each patient identified by screening, a palliative care team reviewed the medical record and provided written recommendations when other treatments might improve the patient's physical symptoms. Of 629 patients screened, 87 (14%) initially met the positive screening criteria. Fifteen (17%) were false positive due to psychiatric symptoms without physical symptoms or due to misrecording. Of 72 cases with actual discomfort, 33 had already been referred to the palliative care team, 14 had received adequate palliative care as determined by the palliative care team, 14 had self-limiting transient discomfort, and one patient died before the screening day. In the remaining 10 cases (11% of symptomatic patients, 1.7% of all screened patients), the palliative care team recommended potentially useful interventions for symptom control; seven patients were referred to the palliative care team within one week. The time required for all screening processes was about 30 minutes per week. This experience demonstrates that screening for patient discomfort as the fifth vital sign using an electronic medical recording system can be successfully implemented and may be useful in facilitating early referral of distressing patients to the specialized

Address correspondence to: Tatsuya Morita, MD, Department of Palliative and Supportive Care, Palliative Care Team and Seirei Hospice, Seirei Mikatahara Hospital, 3453 Mikatahara-cho, Hamamatsu,

Shizuoka 433-8558, Japan. E-mail: tmorita@sis.seirei.or.jp

Accepted for publication: May 8, 2007.

palliative care service. J Pain Symptom Manage 2008;35:430–436. © 2008 U.S. Cancer Pain Relief Committee. Published by Elsevier Inc. All rights reserved.

Key Words

Palliative care team, neoplasms, screening, fifth vital sign, pain

Introduction

Multiple empirical studies suggest that health care professionals often underestimate the symptom distress of advanced cancer patients,^{1–4} and the timing of referral to specialized palliative care services might be late.^{5–7} Screening methods to identify patients with considerable distress could be beneficial, encouraging earlier and more appropriate referral to specialized care from additional resources, such as specialized palliative care services. Several empirical studies have suggested the clinical efficacy of such a screening system,^{8–13} but these studies focus on psychological distress rather than physical discomfort and use patient-reported assessment scales. Using patient-rated assessment scales is essential to receive accurate information about patient distress, but in busy clinical practice, the screening procedure itself may be a burden to both patients and medical professionals.

The American Pain Society describes pain as the fifth vital sign and recommends that clinicians assess patients for pain every time they check the pulse, blood pressure, temperature, and respiration.¹⁴ If all patients receive such “screening” at every vital signs check, this would contribute to better symptom control by identifying patients with undertreated pain, with minimum burden to patients and clinicians. To our knowledge, however, empirical studies have not confirmed the clinical usefulness of such a screening system.^{15,16}

The aim of this report is to describe the feasibility and potential clinical usefulness of screening for patient discomfort as the fifth vital sign using an electronic medical recording system to identify patients with undertreated physical symptoms.

Patients and Methods

Selecting the Screening Tool

The primary aim of this study was to identify patients with considerable *physical* discomfort.

Patient discomfort was conceptualized as any physical symptom, such as pain, dyspnea, nausea, fatigue, and constipation. The rationale to target multiple symptoms, in addition to pain, was their high prevalence and considerable impact on patients' quality of life.^{17–20} We decided not to include psychological symptoms, despite their well-acknowledged importance in patients' quality of life, because (1) routine assessment of multiple items would be a significant burden to nurses as the first step of our project, and (2) medical professionals cannot always provide proxy assessment of patients' psychological distress.^{1–4}

We developed the following screening methodology: Nurses recorded the intensity of discomfort of all patients at every vital signs check (routinely three times per day) using Item 2 of the Support Team Assessment Schedule Japanese version (STAS).^{21–24} The STAS is a well-established comprehensive outcome measurement tool rated by medical professionals, and Item 2 rates the intensity of patients' physical symptoms as 0 (none), 1 (mild), 2 (moderate), 3 (severe), or 4 (extreme). The rationale for selecting the STAS was as follows: (1) the STAS has established reliability and validity for the Japanese population;²⁴ (2) the STAS requires no active participation from and causes no additional burden to patients; (3) the STAS is applicable for all patients including the physically very ill and cognitively impaired who could not complete self-reported questionnaires; (4) rating using Item 2 requires only several seconds and would cause minimum burden to nurses; and (5) the STAS was adopted as a standardized assessment scale for clinical use throughout the hospital, not only for the present study.

We applied the electronic medical recording system so that all admitted patients received routine nurse assessment of patient discomfort. Figure 1 demonstrates that the levels of patient discomfort are visualized on the electronic medical recording system along with the vital sign data. Furthermore, we developed

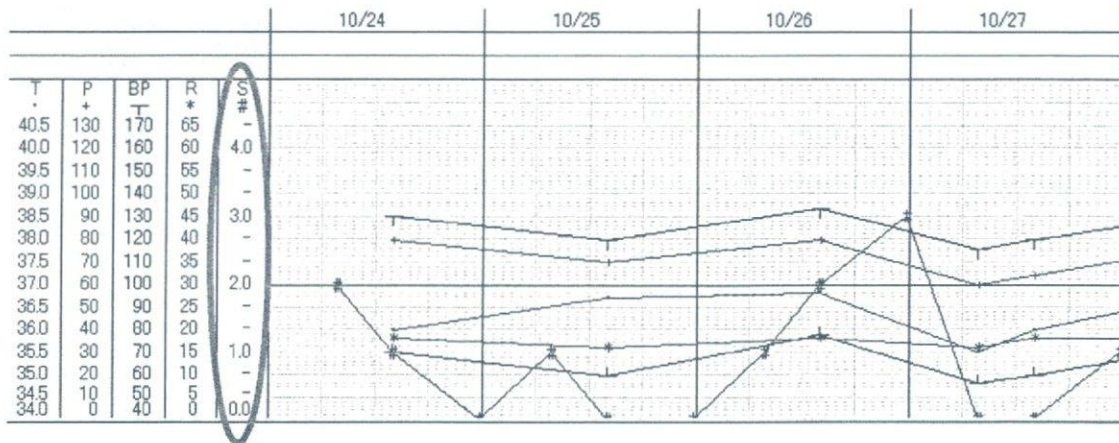


Fig. 1. Patient discomfort visualized as the fifth vital sign.

a computer-based program to automatically screen the scores of the STAS of all admitted patients and list the patients censored (Fig. 2). This procedure required only a few minutes. This system development required only minimum in-house modifications, and no additional costs were incurred.

For the clinical implementation of this system, we conducted multiple educational sessions for all nurses over six months, and distributed the rating instructions via the Web and written portable materials for each nurse.

Screening and Palliative Care Team Intervention

Just after ending the educational sessions, during August to October 2006, all cancer

patients admitted to seven oncology units were automatically screened with the electronic medical recording system at one-week intervals. Each automatic screening required only a few minutes. Patients who had undergone surgery during the previous two weeks were excluded.

We defined positive screening as patients with a STAS score of 2 or more at least two times in the previous one week. We determined this ad hoc cutoff point after several explorative testing phases whereby stricter criteria (i.e., STAS score of 3 or more) detected only a small number of patients.

For all patients identified by automatic screening, the palliative care team reviewed each patient's medical records, with help

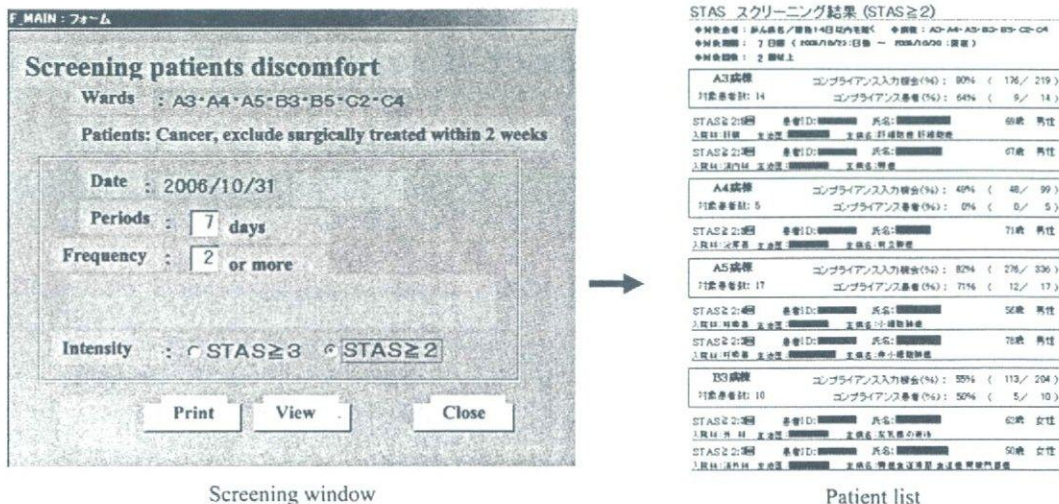


Fig. 2. Computer-based screening system.

from ward nurses, to determine (1) whether the patient actually suffered physical discomfort and (2) whether the patient had already received maximum palliative care medical intervention. If the palliative care team determined that additional treatments might improve the patient's physical symptoms, written recommendations were made in the medical record. This process required about 3 minutes for each patient.

For patients whose palliative care physicians provided written recommendations, primary physicians' adherence to recommendations was followed up one week later.

Palliative Care System in the Seirei Mikatahara General Hospital

The palliative care team that provided specialist input for this study is well established. The Seirei Mikatahara General Hospital is a local cancer center with about 700 beds. The resources of the palliative care division include an inpatient hospice (palliative care unit, 27 beds; four attending physicians and 27 nurses) and a specialized palliative care consultation service (150–200 consultation activities per year; one attending physician and two certified nurses) and receives regular support from liaison psychiatry, a pain service, rehabilitation, oral care, nutrition, social work division, and home-care groups. Symptom control manuals are available via the hospital home page. The clinical activity of the palliative care team has been generally recognized, and thus the

existing human network could have played a screening role before the beginning of this study (e.g., if a pharmacist notices a patient with unrelieved pain, he/she could freely call the palliative care specialist by phone and receive advice within 24 hours).

Results

In this nine-week study period, nurses completed 8,713 assessments of the 11,697 opportunities to apply the STAS (overall compliance rate, 74%). Of the 629 case records screened, 87 cases (14%) initially met the positive screening criteria, that is, a STAS score of 2 or more at least two times during the previous week (Fig. 3). The time required for screening was estimated to be about 30 minutes per week (87 cases/9 sessions, 3 minutes/patient).

Of 87 cases initially screened as positive, 15 (17%) were false positive due to psychiatric symptoms without physical symptoms ($n=13$) and misrecording ($n=2$). Thus, 72 of the 87 cases (83% of positive-screened patients, 11% of all screened patients) had actual physical symptoms.

Of 72 cases with actual discomfort, 33 had already been referred to the palliative care team, 14 had self-limiting transient discomfort, 14 received adequate palliative care as determined by the palliative care team, and one patient died before the screening day. Transient discomfort was related to (1) invasive procedures

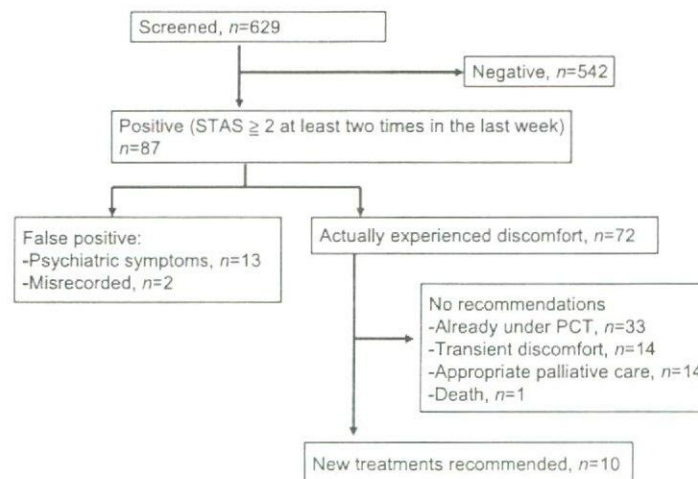


Fig. 3. Results.

(e.g., chest tube, percutaneous biliary drainage, and intubation), (2) radiation or chemotherapy-induced nausea, diarrhea, and fatigue, or (3) benign complications (e.g., pneumonia, gastric ulcer, and cholangitis).

In the remaining 10 cases (11% of symptomatic patients, 1.7% of all screened patients), the palliative care team recommended potentially useful interventions for symptom control, and seven patients were ultimately referred to the palliative care team within one week (Table 1). The majority of cases had complicated and/or multiple physical symptoms, such as neuropathic pain, a combination of pain and delirium, and pain and nausea. All three patients for whom the palliative care team recommended potentially useful interventions but did not refer them to the palliative care team received the recommended treatments by primary physicians.

Discussion

This study suggests that a screening system for patient discomfort as the fifth vital sign using an electronic medical recording system is feasible and may be useful to identify patients with undertreated physical symptoms. The greatest advantage of such a system is its high feasibility. The system development required no additional cost, and this method caused no patient burden and only a minimal burden to nurses. It is, therefore, applicable in busy

clinical practice settings. Thanks to advanced technology, the computer-based program screened the discomfort levels of all admitted patients within a few minutes. In addition, palliative care specialists could review each patient's records with positive screening results on an average of three minutes (30 minutes per week), as they could see all patient records via a single computer terminal in the office.

The assessment completion ratio was not high (i.e., 74%). We believe this figure is reasonable, however, because this observation was performed just after completing the six-month educational sessions. We have now achieved a greater than 85% completion ratio four months after this initial study period (unpublished data).

Overall, 11% of all screened patients actually experienced physical symptoms, and 11% of them, that is, 1.7% of all screened patients, received potentially useful treatments following written recommendations from palliative care specialists. Ultimately, 70% of the identified patients were referred to the palliative care team within one week. The relatively low percentages of patients with physical symptoms (11% of all patients: 72/629) and the patients with physical symptoms who were not referred to the specialized palliative care service (18% of patients with not-transient physical symptoms: 10/57) are unexpected but welcome findings in this study. The possible interpretations are (1) nurses underestimated patient symptoms and/or (2) the specialized palliative care system had been fully established in our hospital and patients with complicated symptomatology had already been referred to our team. We believe the latter is the most likely because previous studies suggested the increased awareness of the role of the palliative care team in our hospital.^{25,26}

Although we cannot demonstrate empirical data beyond the study aim, potential advantages of this system include (1) checking patient discomfort along with vital signs for all patients in *itself* could increase clinician attention to patient discomfort and contribute to improving patients' quality of life, (2) using the standardized tool STAS throughout the hospital could contribute to improving patient assessment, (3) informing doctors of the activity of the specialized palliative care team via the screening could promote physicians

Table 1
Recommended Interventions by Palliative Care Specialists

Case	Symptoms	Interventions
1	Hiccups	Clonazepam, herbal medicine
2	Neuropathic pain	Oxycodone
3	Neuropathic pain	Neck MRI, radiation, baclofen, oxycodone
4	Nausea, bone pain	Serum calcium, brain MRI, bone CT, epidural block, OR
5	Nausea, delirium	Hydration reduction, antihistamine, somatostatin
6	Abdominal pain	Epidural block, fentanyl
7	Nausea, headache	Brain CT, steroids, OR, antihistamine
8	Nausea, bone pain	Serum calcium, brain CT, antihistamine
9	Bone pain, delirium	Bisphosphonate
10	Abdominal swelling	Steroids, OR

OR = Opioid rotation.

unfamiliar with palliative care to consult our team, and (4) patients very reluctant to disclose their physical discomfort to their physicians may receive some benefits.

A major limitation of this study was the lack of a direct assessment of patient symptoms after screening, and this study, therefore, cannot conclude whether this screening system changed the patient outcome. Second, we excluded psychological and psychiatric symptoms in our initial project, and so the next step is to identify overlooked patient psychological modalities. Also, we did not measure formal psychometric properties as a screening instrument (sensitivity, specificity) due to the study design.

In conclusion, screening for patient discomfort as the fifth vital sign using an electronic medical recording system is feasible and may be useful for facilitating earlier and more appropriate referral of distressed patients to the specialized palliative care service. We believe that the low percentage of identified patients is mainly due to the widespread use of the specialized palliative care service in our hospital, and thus, we strongly encourage further studies to clarify the clinical effectiveness of this system in hospitals in which palliative care team activity has not been sufficiently introduced.

References

1. Sprangers MAG, Aaronson NK. The role of health care providers and significant others in evaluating the quality of life of patients with chronic disease: a review. *J Clin Epidemiol* 1992;45:743–760.
2. Heaven CM, Maguire P. Disclosure of concerns by hospice patients and their identification by nurses. *Palliat Med* 1997;11:283–290.
3. Nekolaichuk CL, Maguire TO, Almazor MS, Rogers WT, Bruera E. Assessing the reliability of patient, nurse, and family caregiver symptom ratings in hospitalized advanced cancer patients. *J Clin Oncol* 1999;17:3621–3630.
4. Horton R. Differences in assessment of symptoms and quality of life between patients with advanced cancer and their specialist palliative care nurses in a home care setting. *Palliat Med* 2002;16:488–494.
5. Christakis NA, Escarce JJ. Survival of Medicare patients after enrollment in hospice programs. *N Engl J Med* 1996;335:172–178.
6. Costantini M, Toscani F, Gallucci M, et al. Terminal cancer patients and timing of referral to palliative care: a multicenter prospective cohort study. *J Pain Symptom Manage* 1999;18:243–252.
7. Morita T, Akechi T, Ikenaga M, et al. Late referrals to specialized palliative care service in Japan. *J Clin Oncol* 2005;23:2637–2644.
8. Carlson LE, Specca M, Hagen N, Taenzer P. Computerized quality-of-life screening in a cancer pain clinic. *J Palliat Care* 2001;17:46–52.
9. Lloyd-Williams M, Friedman T, Rudd N. An analysis of the validity of the Hospital Anxiety and Depression scale as a screening tool in patients with advanced metastatic cancer. *J Pain Symptom Manage* 2001;22:990–996.
10. Barg FK, Cooley M, Pasacreta J, Senay B, McCorkle R. Development of a self-administered psychosocial cancer screening tool. *Cancer Pract* 1994;2:288–296.
11. Shimizu K, Akechi T, Okamura M, et al. Usefulness of the nurse-assisted screening and psychiatric referral program. *Cancer* 2005;103:1949–1956.
12. Jacobsen PB, Donovan KA, Trask PC, et al. Screening for psychologic distress in ambulatory cancer patients. *Cancer* 2005;103:1494–1502.
13. Akizuki N, Akechi T, Nakanishi T, et al. Development of a brief screening interview for adjustment disorders and major depression in patients with cancer. *Cancer* 2003;97:2605–2613.
14. Available at <http://www.ampainsoc.org>. Accessed on December 2, 2006.
15. Merboth MK, Barnason S. Managing pain: the fifth vital sign. *Nurs Clin North Am* 2000;35:375–383.
16. Lynch M. Pain as the fifth vital sign. *J Intraven Nurs* 2001;24:85–94.
17. Morita T, Tsunoda J, Inoue S, Chihara S. Contributing factors to physical symptoms in terminally-ill cancer patients. *J Pain Symptom Manage* 1999;18:338–346.
18. Mercadante S, Casuccio A, Fulfarò F. The course of symptom frequency and intensity in advanced cancer patients followed at home. *J Pain Symptom Manage* 2000;20:104–112.
19. Walsh D, Donnelly S, Rybicki L. The symptoms of advanced cancer: relationship to age, gender, and performance status in 1000 patients. *Support Care Cancer* 2000;8:175–179.
20. Skaug K, Eide GE, Gulsvik A. Prevalence and predictors of symptoms in the terminal stage of lung cancer: a community study. *Chest* 2007;131:389–394.
21. Carson MG, Fitch MI, Vachon ML. Measuring patient outcomes in palliative care: a reliability and validity study of the Support Team Assessment Schedule. *Palliat Med* 2000;14:25–36.
22. Hodgson C, Higginson I, McDonnell M, Butters E. Family anxiety in advanced cancer:

a multicentre prospective study in Ireland. *Br J Cancer* 1997;76:1211–1214.

23. Edmonds PM, Stuttaford JM, Penny J, Lynch AM, Chamberlain J. Do hospital palliative care teams improve symptom control? Use of a modified STAS as an evaluation tool. *Palliat Med* 1998; 12:345–351.

24. Miyashita M, Matoba K, Sasahara T, et al. Reliability and validity of the Japanese version of the

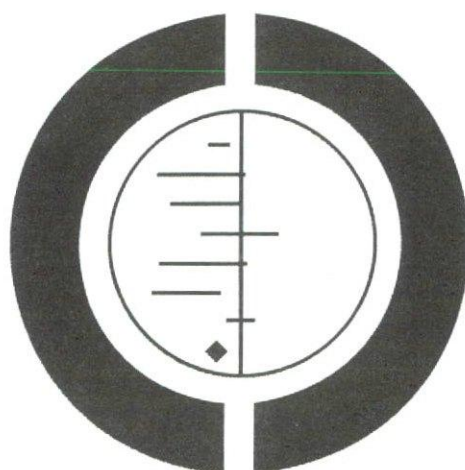
support team assessment schedule (STAS-J). *Palliat Support Care* 2004;2:379–385.

25. Morita T, Yo T, Fujimoto M. Palliative care team: the first year audit in Japan. *J Pain Symptom Manage* 2005;29:458–465.

26. Morita T, Imura C, Fujimoto K. Trends toward earlier referrals to a palliative care team. *J Pain Symptom Manage* 2005;30:204–205.

Psychotherapy for depression among incurable cancer patients (Review)

Akechi T, Okuyama T, Onishi J, Morita T, Furukawa TA



**THE COCHRANE
COLLABORATION®**

This is a reprint of a Cochrane review, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2008, Issue 3

<http://www.thecochranelibrary.com>



Psychotherapy for depression among incurable cancer patients (Review)
Copyright © 2008 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd

1

TABLE OF CONTENTS

ABSTRACT	1
PLAIN LANGUAGE SUMMARY	2
BACKGROUND	2
OBJECTIVES	2
CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW	2
SEARCH METHODS FOR IDENTIFICATION OF STUDIES	3
METHODS OF THE REVIEW	4
DESCRIPTION OF STUDIES	5
METHODOLOGICAL QUALITY	6
RESULTS	6
DISCUSSION	7
AUTHORS' CONCLUSIONS	8
POTENTIAL CONFLICT OF INTEREST	9
ACKNOWLEDGEMENTS	9
SOURCES OF SUPPORT	9
REFERENCES	9
TABLES	11
Characteristics of included studies	11
Characteristics of excluded studies	14
ADDITIONAL TABLES	15
Table 01. Additional search strategies	15
ANALYSES	19
Comparison 01. Psychotherapy versus treatment as usual	19
Comparison 02. Subgroup analyses	19
Comparison 03. Sensitivity analyses	19
COVER SHEET	19
GRAPHS AND OTHER TABLES	21
Figure 01. Funnel plot for the outcome depression	21
Figure 02. Funnel plot for the outcome anxiety	22
Figure 03. Funnel plot for the outcome total mood disturbance	23
Analysis 01.01. Comparison 01 Psychotherapy versus treatment as usual, Outcome 01 Depression	24
Analysis 01.02. Comparison 01 Psychotherapy versus treatment as usual, Outcome 02 Anxiety	24
Analysis 01.03. Comparison 01 Psychotherapy versus treatment as usual, Outcome 03 Total Mood Disturbance	25
Analysis 02.01. Comparison 02 Subgroup analyses, Outcome 01 Depression	25
Analysis 02.02. Comparison 02 Subgroup analyses, Outcome 02 Anxiety	26
Analysis 02.03. Comparison 02 Subgroup analyses, Outcome 03 Total Mood Disturbance	26
Analysis 03.01. Comparison 03 Sensitivity analyses, Outcome 01 Depression	27

Psychotherapy for depression among incurable cancer patients (Review)

Akechi T, Okuyama T, Onishi J, Morita T, Furukawa TA

This record should be cited as:

Akechi T, Okuyama T, Onishi J, Morita T, Furukawa TA. Psychotherapy for depression among incurable cancer patients. *Cochrane Database of Systematic Reviews* 2008, Issue 2. Art. No.: CD005537. DOI: 10.1002/14651858.CD005537.pub2.

This version first published online: 23 April 2008 in Issue 2, 2008.

Date of most recent substantive amendment: 11 February 2008

ABSTRACT

Background

The most common psychiatric diagnosis among cancer patients is depression; this diagnosis is even more common among patients with advanced cancer. Psychotherapy is a patient-preferred and promising strategy for treating depression among cancer patients. Several systematic reviews have investigated the effectiveness of psychological treatment for depression among cancer patients. However, the findings are conflicting, and no review has focused on depression among patients with incurable cancer.

Objectives

To investigate the effects of psychotherapy for treating depression among patients with advanced cancer by conducting a systematic review of randomized controlled trials (RCTs).

Search strategy

We searched the Cochrane Pain, Palliative and Supportive Care Group Register, The Cochrane Controlled Trials Register, MEDLINE, EMBASE, CINAHL, and PsycINFO databases in September 2005.

Selection criteria

All relevant RCTs comparing any kind of psychotherapy with conventional treatment for adult patients with advanced cancer were eligible for inclusion. Two independent review authors identified relevant studies.

Data collection and analysis

Two review authors independently extracted data from the original reports using standardized data extraction forms. Two independent review authors also assessed the methodological quality of the selected studies according to the recommendations of a previous systematic review of psychological therapies for cancer patients that utilized ten internal validity indicators. The primary outcome was the standardized mean difference (SMD) of change between the baseline and immediate post-treatment scores.

Main results

We identified a total of ten RCTs (total of 780 participants); data from six studies were used for meta-analyses (292 patients in the psychotherapy arm and 225 patients in the control arm). Among these six studies, four studies used supportive psychotherapy, one adopted cognitive behavioural therapy, and one adopted problem-solving therapy. When compared with treatment as usual, psychotherapy was associated with a significant decrease in depression score (SMD = -0.44, 95% confidence interval [CI] = -0.08 to -0.80). None of the studies focused on patients with clinically diagnosed depression.

Authors' conclusions

Evidence from RCTs of moderate quality suggest that psychotherapy is useful for treating depressive states in advanced cancer patients. However, no evidence supports the effectiveness of psychotherapy for patients with clinically diagnosed depression.

PLAIN LANGUAGE SUMMARY

Psychotherapy for depression among cancer patients who are incurable

Depressive states represent frequent complications among cancer patients and are more common amongst advanced cancer patients. Psychotherapy comprises of various interventions for ameliorating or preventing psychological distress conducted by direct verbal or interactive communication, or both, and is delivered by health care professionals. It is a patient-preferred and promising strategy for treating depressive states among cancer patients. Several systematic reviews have investigated the effectiveness of psychotherapy for treating depressive states among cancer patients. However, the findings are conflicting, and no review has focused on depressive states among patients with incurable cancer. The review authors conducted a systematic review of randomised controlled trials to investigate the effects of psychotherapy on the treatment of depressive states among patients with advanced cancer. The review authors found that psychotherapy was useful for treating depressive states in advanced cancer patients. However, little evidence supports the effectiveness of psychotherapy for patients with clinically diagnosed depression including major depressive disorder. Future studies to investigate and clarify the usefulness of psychotherapy for treating clinically diagnosed depression in terminally ill patients are needed.

BACKGROUND

Cancer is a life-threatening disease that often impacts on a patient's welfare and well-being; attention to these issues is thus an important aspect of comprehensive patient care. Derogatis *et al.* found that 50% of cancer patients are diagnosed with a psychiatric disorder. The most common psychiatric diagnosis was depressive disorders, including adjustment disorder with depressed mood (12%) or mixed emotional features (13%) or unipolar major depression, (4%) or both (Derogatis 1983). Other studies have consistently indicated that these depressive disorders represent common forms of psychological distress experienced by cancer patients (Akechi 2001; Kugaya 2000; Okamura 2000) and are more common in patients with advanced cancer (Bukberg 1984; Kugaya 2000). Thus depression is one of the most widely recognized psychiatric disorders in cancer patients (McDaniel 1995). Depression not only produces serious suffering (Block 2000), but also worsens quality of life (Grassi 1996), reduces compliance with anti-cancer treatment (Colleoni 2000), can lead to suicide (Henriksson 1995), is a psychological burden on the family (Cassileth 1985), and prolongs hospitalization (Prieto 2002). Thus, the appropriate management of depression in cancer patients is critically important.

One patient-preferred and promising strategy for treating depression among cancer patients is psychotherapy (Okuyama 2007). Here, the term 'psychotherapy' is defined as various kinds of interventions for ameliorating or preventing psychological distress conducted by direct verbal or interactive communication, or both, delivered by health care professionals. Several meta-analyses and systematic reviews investigating the effectiveness of psychosocial treatment for depression among cancer patients have been performed. However, the findings of these reports are conflicting (Devine 1995; Newell 2002; Ross 2002; Sheard 1999), and no review to date has addressed the effectiveness of psychotherapy for treating depression among incurable cancer patients.

OBJECTIVES

- 1) The primary objective of this review was to investigate the effectiveness of psychotherapy for treating any kind of depression in incurable cancer patients.
- 2) The review also evaluated the effectiveness of psychotherapy on:

- anxiety,
- general psychological distress,
- control of cancer symptoms,
- quality of life,
- coping measures for patients,
- severity of physical symptoms such as pain.

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

Types of studies

All relevant randomised controlled trials (RCTs) comparing any kind of psychotherapy with conventional treatment (treatment as usual).

Types of participants

The study participants were limited to adults (18 years or older) of either sex with any primary diagnosis of incurable cancer. Their depression had to be assessed by validated measures, such as standardized self-report questionnaires or clinical interviews (e.g., Structured Clinical Interview for major depressive episode based on DSM-IV). A concurrent diagnosis of another physical disease was not a criteria for exclusion.

Types of intervention

Studies involving psychotherapy of any kind were included in the review. We were interested in the effect of a broad range of psychological interventions, including several unique interventions, such as music therapy, that may be used in a palliative care setting. On the other hand, interventions that were not considered as forms of psychotherapy (e.g., aromatherapy, therapeutic touch) were not included. This broad range of non-pharmacological interventions were further divided into:

A: interventions by direct verbal or interactive communication, or both, delivered by health care professionals; and

B: non-pharmacological interventions other than the aforementioned ones.

Types of outcome measures

The studies had to include at least one measure of the severity of depression, which was set as the primary outcome of this systematic review. Symptom severity could be measured either by self-reporting or rating by an observer.

Effectiveness was to be evaluated using the group mean scores of these continuous depression severity scales (this planned analytical method was modified in the completed review (See 'Results')).

Outcomes were to be measured at the end of the study. Where possible, these indices of effectiveness would be pooled at different time points in the course of treatment, such as at one month, three months, six months and so on. In addition, when studies provided data regarding ongoing effectiveness after treatment termination, this data was also to be pooled (this planned method was modified (See 'data synthesis')).

Secondary outcomes were as follows:

- 1) no of patients who 'responded' to treatment according to the original study authors' definition;
- 2) anxiety, as measured using scales like the Hamilton Anxiety Rating scale, the State-Trait Anxiety Inventory, and the Hospital Anxiety and Depression Scale;
- 3) general psychological distress, as measured using scales like the Profile of Mood States (total mood disturbance) and the General Health Questionnaire;
- 4) quality of life, as measured using scales like the European Organization for Research and Treatment of Cancer (EORTC) quality of life questionnaire, the Functional Assessment of Cancer Therapy-General (FACT-G) scale, and the Medical Outcome Study Short-Form 36-item survey;
- 5) severity of physical symptoms like pain, as measured using scales like the Brief Pain Inventory (BPI) and visual analogue scale (VAS).

Tolerability of the treatment was to be evaluated using the following outcome measures:

- 1) Number of patients dropping out of the study for any reason.

SEARCH METHODS FOR IDENTIFICATION OF STUDIES

See: Cochrane Pain, Palliative and Supportive Care Group methods used in reviews.

1. Electronic databases

To identify studies for inclusion in this review, detailed search strategies were developed for each electronic database searched in September 2005. These strategies were based on the search strategy developed for MEDLINE but were revised appropriately for each database and are included in additional Table 01.

MEDLINE via OVID search strategy

1. exp PSYCHOTHERAPY/
2. (psychotherap\$ or aromatherap\$ or "art therap\$" or "autogenic training" or "behavior\$ adj6 therap\$" or (behaviour\$ adj6 therap\$) or (biofeedback and psycho\$) or (cognitive adj6 therap\$) or (desensiti\$ and psychol\$) or "implosive therap\$" or (relax\$ adj6 therap\$) or (relax\$ adj6 techniq\$) or (therap\$ adj6 touch\$) or yoga)
3. (bibliotherapy or (color\$ adj6 therap\$) or (colour\$ adj6 therap\$) or (music\$ adj6 therap\$) or (hypno\$ adj6 therap\$) or (imagery and psychotherap\$) or counsel\$ or (group\$ adj6 therap\$) or "socioenvironmental therap\$" or "socio environmental therap\$" or "milieu therap\$" or "therapeutic communit\$" or (famil\$ adj6 therap\$) or psychosoc\$ or psycholog\$ or "self help group\$" or (support\$ adj6 group\$) or (guide\$ adj6 image\$))
4. or/1-3
5. Depression/
6. (depression or depressive\$ or depressed)
7. or/5-6
8. exp NEOPLASMS/
9. (tumor\$ or tumour\$ or cancer\$ or carcinoma\$ or malignan\$ or neoplas\$)
10. or/8-9
11. 4 and 7 and 10

The above search strategy was run with the following filter for Controlled Clinical Trials:

Cochrane Sensitive Search strategy for RCTs for MEDLINE on OVID (published in appendix 5b Cochrane Handbook for Systematic Reviews of Interventions. 4.2.5 May 2005)

1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. randomized controlled trials.sh.
4. random allocation.sh.
5. double blind method.sh.
6. single blind method.sh.
7. or/1-6
8. (ANIMALS not HUMAN).sh.
9. 7 not 8
10. clinical trial.pt.

11. exp clinical trials/
12. (clin\$ adj25 trial\$).ti,ab.
13. ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj25 (blind\$ or mask\$)).ti,ab.
14. placebos.sh.
15. placebo\$.ti,ab.
16. random\$.ti,ab.
17. research design.sh.
18. or/10-17
19. 18 not 8
20. 19 not 9
21. 9 or 19

2. Reference search

The references of all selected studies were inspected for more published reports and citations of unpublished studies. In addition, other relevant review papers were checked.

3. SciSearch

All the selected studies were sought as a citation in the SciSearch database to identify additional studies.

4. Personal communication

To ensure that all RCTs were identified, the authors of significant papers were contacted.

5. Language

No language restrictions were applied when selecting studies.

METHODS OF THE REVIEW

1. Selection of studies

In September 2005, two review authors (TA and JO) checked hard copies of the references identified by the search strategy to identify studies meeting the following broad and simple criteria:

- i) randomised trials;
- ii) incurable cancer patients (this included subjects with incurable, advanced, metastatic, or terminal cancer. When the participants were mixed-stage cancer patients, studies in which more than 80% of the participants had an advanced stage of cancer (stage III, IV, or recurrent) were eligible for inclusion in the review); and
- iii) assessment of depression.

The inter-rater reliability of the two raters were evaluated using percentage agreement and kappa coefficient. All studies identified by either of the two raters were then subjected to the next stage of critical appraisal according to the strict eligibility criteria.

2. Quality assessment

Two independent review authors (TA and TO) assessed the methodological quality of the selected studies. We used Newell's methodological quality criteria (Newell 2002), which includes the following points:

- i) adequate concealment of allocation;
- ii) patients randomly selected;

- iii) patients blinded to treatment group;
- iv) care-providers blinded to treatment group;
- v) except for study intervention, equivalence of other treatments;
- vi) care-providers' adherence monitored;
- vii) detailed lost-to-follow-up information;
- viii) percentage of patients not included in analyses;
- ix) intention-to-treat analyses; and
- x) outcomes measured in a blinding fashion.

The maximum score for each study was 30 points, with higher scores indicating higher quality. As previously reported, the quality of a study was considered to be good if the study had a total score greater than 20 points, fair if it scored 11 to 20 points, and poor if it scored less than 11 points (Newell 2002).

The inter-rater reliability of these validity criteria was evaluated using Cohen's weighted kappa. Those studies with clearly inadequate concealment of random allocation were excluded. The influences of the other quality indices were examined using sensitivity analyses.

3. Data extraction

Two review authors (TA and TO) independently extracted data from the original reports using data extraction forms. Any disagreement was resolved by consensus between the two or, where necessary, between all the review authors. Extracted data included the country of origin, the nature and content of psychological intervention and the patient group involved, the duration of the study, the study setting, the sample size, and the key outcomes using validated instruments.

4. Data synthesis

Planned method

Data were to be entered by JO into Review Manager 4.2.10 twice, using the duplicate data entry feature. For dichotomous outcomes, the relative risk (RR) and their 95% confidence intervals (CI) were to be calculated using the random-effects model, since the RR of the random-effects model has been shown to be superior in clinical interpretability and external generalisability than the fixed-effect models and odds ratios (OR) or risk differences (Furukawa 2002). The heterogeneity among the studies was to be assessed using the I-squared and Q statistics and by visual inspection of the results in the Meta View plots. An I² greater than 30% or a Q statistic P value of less than 0.1 was to be considered indicative of heterogeneity. If significant heterogeneity was suspected, the sources were to be investigated. For dichotomous outcomes of response, two analytical strategies were to be adopted; first, a 'per protocol' analysis was to be performed according to the values reported by the original authors. When data on dropouts were included, usually by way of the last-observation-carried-forward (LOCF) method, this data was to be analysed according to the primary studies. For continuous outcomes, the standardized mean difference (SMD) was to be pooled using the random-effects model. Continuous outcomes were to be analysed on an endpoint basis, including only patients with a final assessment or with a last