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Fig. 17 Kaplan—Meier survival of resected cases stratified by curative potential of gastric resection

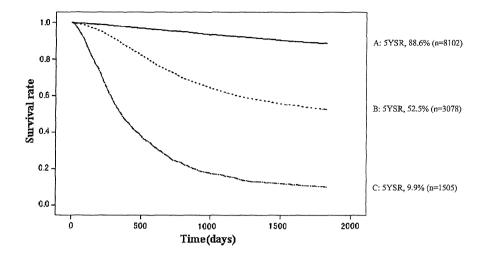
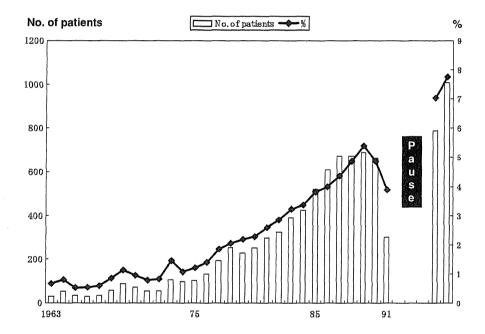


Fig. 18 Chronological change of gastric cancer patients older than 80 years. The nationwide registry was suspended for a decade from 1992



Discussion

Estimates of the worldwide incidence, mortality, and prevalence of 26 cancers in the year 2002 were available in the GLOBOCAN series of the International Agency for Research on Cancer [4]. With an estimated 934,000 new cases per year in 2002 (8.6 % of new cancer cases), the incidence of stomach cancer is in fourth place, after cancers of the lung, breast, and colon and rectum. It is the second most common cause of death from cancer (700,000 deaths annually).

The data presented in this report were collected from 208 hospitals in Japan. Cancer incidence rate (annual number of newly diagnosed cases per 100,000 population)

in Japan in 2002 was approximately 520 for males and 370 for females. The incidences of various cancers in Japan are estimated from data collected by the cancer registry system in a dozen prefectures. According to these statistics, the number of cancer incidences in 2002 was approximately 589,000. The stomach was the leading site (21 %) for males and the second highest site (14 %) for females. The number of new patients who were diagnosed as gastric cancer in 2002 was estimated to be 106,760 [5]. Accordingly, 13,626 patients registered by this program corresponded to approximately 13 % of the whole population affected by gastric cancer in Japan. Even though these patients may not represent the average features of gastric cancer found in this country, this report is considered to



have analyzed the largest number of patients for the past 10 years, clarifying the trends of gastric cancer in Japan. Just for reference, the proportion of patients registered in the nationwide registry of other organs of all patients diagnosed were 6 % in colon cancer, 24 % in esophageal cancer, 25 % in liver cancer, and 26 % in lung cancer, respectively [6].

The reliability of the results in this report depends on the quality of data accumulated in the JGCA database. Because of the complexity of the JGCA staging system, the error checking system on the data entry screen did not function completely. In several categories such as lymph node metastasis (N), the JGCA system could not be converted to the TNM system automatically. Therefore, the registration committee had to make great efforts to confirm raw data sent to the data center from the participating hospitals.

As compared with our archived data of 12,004 patients treated in 2001 [1], the proportion of early cancer declined from 51.2 % to 49.7 % [pT1 (M) cancer, 27.4 % to 25.6 %, and pT1 (SM) cancer, 23.8 % to 24.1 %], suggesting that an increasing number of patients with mucosal cancer were sent for endoscopic treatment. These data suggest that we should start to register gastric patients treated with endoscopic mucosal resection (EMR) and/or endoscopic submucosal dissection (ESD) as soon as possible. The surgical mortality within 30 days significantly improved, from 0.6 % to 0.48 % (P < 0.001). Just for reference, it was 4.0 % in 1963 and 1.0 % in 1991 [7], Moreover, the nationwide database of gastrointestinal surgery in 2008 showed that was 0.2 % in gastrectomy and 0.4 % in total gastrectomy [8].

Accordingly with the rapidly aging society in Japan, the proportion of patients more than 80 years old continued increasing (Fig. 18): it was 0.7 % in 1963, 4.9 % in 1990, 7.0 % in 2001, and 7.8 % in 2002, respectively. Although the risk for surgery increases in elderly patients who have comorbidities, evaluations of risk can allow interventions that may decrease morbidity and mortality. Appropriate treatments should be offered to the elderly. However, these data have the intrinsic weakness of being retrospectively collected 7 years after surgery. Unfortunately, we in Japan continue to have a legal difficulty in registering personal information, which is essential for long-term and prospective follow-up. The overall follow-up rate in our program was 83.5 %. In other words, the outcome of 17.5 % of the patients is unknown. The proportion of patients who were lost to follow-up in the Japanese nationwide registry of colon cancer, liver cancer, and thyroid cancer was 19.6 %, 25.8 %, and 20.6 %, respectively [6]. Rules and regulations regarding handling of these data will have to change radically to overcome the issue of accuracy and reliability of the nationwide registry in Japan, and this could be out of the hands of the surgeons who have

contributed to the best of their abilities to gather these data. On the other hand, the Japanese Association of Clinical Cancer Centers, consisting of 25 cancer center hospitals, reported that their follow-up rate was 98.5 %, and 5YEARS of 9,980 patients who underwent surgery from 1997 to 2000 were 90.4 % for TNM stage I, 67.8 % for stage II, 43.3 % for stage III, and 9.3 % for stage IV, respectively [9]. When the patients with gastric cancer had a medical examination in clinical cancer centers, they registered the place where their family records were registered, and office workers of the clinical cancer centers confirmed regularly their safety from the family registration; this was the reason for the extremely high follow-up rate. In the current analyses, 5YEARS in stage IV patients was 15.2 %. We might have overestimated our 5YEARS in stage IV patients, but we found that our follow-up rate increased as the stage advanced; the follow-up rate of stage IV patients was 90.4 %. These data suggest that the lower follow-up rate may not have had serious effects on 5YE-ARSs in our program. Although, the correlation between follow-up rate and survival rate is complicated, our followup system needs to be improved if we are to evaluate the survival rates more accurately.

Cytological examination was conducted in 3,481 (59.4 %) of 5,857 patients with T2, T3, or T4 cancer. The 5YEARS of CY1 patients was 12.3 % and their 5YEARS was as poor as that of patients with peritoneal metastasis. Although this examination was not carried out commonly in the days of 2002, it could still be regarded as a significant and independent prognostic factor from the data that were available. These findings further support the need for staging laparoscopy for accurate preoperative staging in patients with advanced gastric cancer.

JGCA restarted a nationwide registration from 2008. The object of the new nationwide registry was primarily to calculate the stage-specific 5YEARSs among patients who underwent gastrectomy. Therefore, the structure of the database was required to be simple, and the number of registration items was kept to a minimum. Undoubtedly, the next objective would be to collect and analyze data of patients with inoperable disease, remnant gastric cancer, gastrointestinal stromal tumor, malignant lymphoma of the stomach, and other entities that were excluded in the current project. We also began to register patients who were treated by EMR/ESD by adding additional items and updating data entry software from 2011.

We hope that this report will be useful when surveying trends and changes in the clinical practice and treatment results of gastric cancer in Japan. Details of the individual data presented in this report will soon become available for scientific and clinical research with the permission of the registration committee. In addition, most of the surgical and pathological data could easily be transferred to the



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international database in the near future for various analyses. The registration committee will continue the efforts to improve the registration system, ultimately to collect meaningful annual data.

Acknowledgments The JGCA Registration Committee appreciates the great effort of participating hospitals in registering accurate and detailed data for this project. I wish to express my great gratitude to Ms. Yoshimi Sugamura, Niigata University Medical and Dental Hospital, for her valuable assistance.

Conflict of interest The authors declare that there are no conflicts of interest related to the contents of this manuscript.

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Appendix: Participating hospitals

Data of gastric cancer patients in this report were collected from the surgical or gastrointestinal departments of the following 208 hospitals (in alphabetical order): Akashi Municipal Hospital, Aomori City Hospital, Asahikawa Medical University Hospital, Cancer Institute Hospital, Chiba Cancer Center, Chiba University Hospital, Dokkyo Medical University Hospital, Ebina General Hospital, Fuchu Hospital, Fujita Health University (Banbuntane Houtokukai Hospital), Fukaya Red Cross Hospital, Fukui Red Cross Hospital, Fukuoka University Chikushi Hospital, Fukuoka University Hospital, Fukushima Medical University Hospital, Gifu Prefectural General Medical Center, Gifu University Hospital, Gunma Prefectural Cancer Center, Gunma University Hospital, Hakodate Goryoukaku Hospital, Hakodate Municipal Hospital, Hamamatsu University School of Medicine, University Hospital, Handa City Hospital, Health Insurance Hitoyoshi General Hospital, Higashiosaka City General Hospital, Himeji Central Hospital, Hiroshima City Asa Hospital, Hiroshima City Hospital, Hiroshima Prefectural Hospital, Hiroshima Red Cross Hospital and Atomic-bomb Survivors Hospital, Hiroshima University Hospital, Hitachi General Hospital, Hokkaido University Hospital, Hoshigaoka Koseinenkin Hospital, Hospital, University of the Ryukyus, Hyogo Cancer Center, Hyogo Prefectural Nishinomiya Hospital, Ibaraki Prefectural Central Hospital, Ibaraki Seinan Medical Center Hospital, Ishikawa Prefectural Central Hospital, Iwate Medical University Hospital, Iwate Prefectural Central Hospital, Iwate Prefectural Kamaishi Hospital, Izumi Municipal Hospital, JA Hiroshima Kouseiren Hiroshima General Hospital, Japanese Red Cross Medical Center, Jikei University School of Medicine, Jikei

University Aoto Hospital, Juntendo University Juntendo Hospital, Jusendo Medical Hospital, Kagawa Prefectural Central Hospital, Kagawa Medical University Hospital, Kakogawa Municipal Hospital, Kanagawa Cancer Center, Kanazawa University Hospital, Kansai Electric Power Hospital, Kansai Rousai Hospital, Kawasaki Medical School Hospital, Keio University Hospital, Keiyukai Sapporo Hospital, Kimitsu Chuo Hospital, Kinki Central Hospital, Kinki University Hospital, Kiryu Kosei General Hospital, Kitakyushu Municipal Medical Center, Kobe Century Memorial Hospital, Kobe City Medical Center General Hospital, Kouchi Medical School Hospital, Kumamoto Medical Center, Kumamoto Regional Medical Center, Kumamoto University Hospital, Kurashiki Central Hospital, Kurobe Kyosai Hospital, Kuroishi General Hospital, Kurume University Hospital, Kushiro Rosai Hospital, Kyorin University Hospital, Kyoto Second Red Cross Hospital, Kyoto University Hospital, Kyushu University Hospital, Matsushita Memorial Hospital, Matsuyama Red Cross Hospital, Misawa City Hospital, Mitoyo General Hospital, Miyagi Cancer Center, Mizushima Kyodo Hospital, Muroran City General Hospital, Musashino Red Cross Hospital, Nagahama City Hospital, Nagano Municipal Hospital, Nagano Red Cross Hospital, Nagaoka Chuo General Hospital, Nagasaki Municipal Hospital, Nagoya University Hospital, Nakagami Hospital, Nanpuh Hospital, Nara Medical University Hospital, Nara Hospital, Kinki University Faculty of Medicine, National Cancer Center Hospital, National Defense Medical College Hospital, NHO Ciba Medical Center, NHO Kasumigaura Medical Center, NHO Kyushu Cancer Center, NHO Osaka Medical Center, NHO Sendai Medical Center, NHO Shikoku Cancer Center, NHO Tokyo Medical Center, NHO Yokohama Medical Center, Nihon University Itabashi Hospital, Nihon University Surugadai Hospital, Niigata Cancer Center Hospital, Niigata City General Hospital, Niigata Prefectural Shibata Hospital, Niigata Prefectural Yoshida Hospital, Niigata University Medical and Dental Hospital, Nippon Koukan Hospital, Nippon Medical School Chiba Hokusoh Hospital, Nippon Medical School Hospital, Nishi-kobe Medical Center, NTT West Osaka Hospital, Obihiro Tokushukai Hospital, Oita Red Cross Hospital, Oita University Hospital, Okayama University Hospital, Okitama Public General Hospital, Onomichi Municipal Hospital, Osaka City University Hospital, Osaka General Medical Center, Osaka Kouseinenkin Hospital, Osaka Medical Center for Cancer and Cardiovascular Diseases, Osaka Medical College Hospital, Osaka Police Hospital, Osaka Red Cross Hospital, Osaka Seamen's Insurance Hospital, Osaka University Hospital, Otsu Municipal Hospital, Otsu Red Cross Hospital, Rinku General Medical Hospital, Sado General Hospital, Saga University Hospital, Saiseikai Chuwa Hospital, Saiseikai Fukuoka General



Hospital, Saiseikai Kumamoto Hospital, Saiseikai Niigata Daini Hospital, Saiseikai Noe Hospital, Saiseikai Utsunomiya Hospital, Saitama Medical Center, Saitama Medical Center Jichi Medical University, Saitama Red Cross Hospital, Saitama Social Insurance Hospital, Saku Central Hospital, Sapporo City General Hospital, Sapporo Medical Center, Sapporo Medical University Hospital, Sapporo Social Insurance General Hospital, Sayama Hospital, Seirei Hamamatsu General Hospital, Shakaihoken Kobe Central Hospital, Shiga University of Medical Science Hospital, Shimonoseki City Central Hospital, Shinnittetsu Yahata Memorial Hospital, Shinshu University Hospital, Shizuoka Cancer Center, Showa Inan Hospital, Showa University Northern Yokohama Hospital, Showa University Toyosu Hospital, Social Insurance Central General Hospital, Social Insurance Kinan Hospital, Southern Tohoku General Hospital, St. Luke's International Hospital, St. Marianna University School of Medicine Yokohama City West Hospital, Suita Municipal Hospital, Sumitomo Hospital, Suwa Red Cross Hospital, Takeda General Hospital, Tochigi Cancer Center, Toho University Ohashi Medical Center, Tohoku University Hospital, Tokushima Municipal Hospital, Tokushima Prefectural Central Hospital, Tokushima University Hospital, Tokyo Medical University Ibaraki Medical Center, Tokyo Metropolitan Bokutoh Hospital, Tokyo Metropolitan Cancer and Infectious Disease Center Komagome Hospital, Tokyo Women's Medical University (Institute of Gastroenterology), Tokyo Women's Medical University Hospital, Tokyo Women's Medical University Medical Center East, Tonami General Hospital, Toranomon Hospital, Tottori Municipal Hospital, Toyama Prefectural Central Hospital, Toyama University Hospital, Toyohashi Municipal Hospital, Tsuchiura Kyodo General Hospital, Tsukuba University Hospital, University Hospital Kyoto Prefectural University of Medicine, University of Fukui Hospital, University of Miyazaki Hospital, University of Yamanashi Wakayama Medical University Hospital, Hospital,

Yamachika Memorial General Hospital, Yamagata Prefectural Central Hospital, Yamagata University Hospital, Yamaguchi Rousai Hospital, Yamanashi Prefectural Central Hospital, Yao Municipal Hospital, Yodogawa Christian Hospital, Yokohama City University Hospital, Yokohama City University Medical Center, and Yuri Kumiai General Hospital.

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Original Article

Troubles and Hardships Faced by Psychologists in Cancer Care

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Objective: The aim of this study was to identify problems experienced by psychologists involved in cancer and palliative care and consider an education system for psychologists. **Methods:** We conducted a questionnaire survey of psychologists involved in cancer care and palliative care. At the 403 facilities, 419 psychologists who received the questionnaire were asked to fill it out anonymously. A total of 294 people (61 male, 233 female, average age \pm SD = 36.3 \pm 9.4) responded about troubles and hardships actually faced by psychologists working in cancer care. We performed qualitative content analysis of free responses. **Results:** We obtained the following five categories: 'Hospital system', 'Psychologist role and

specialization (ambiguity of the role expected of psychologists and problems arising because psychologists are not nationally licensed)', 'Collaboration with other medical professionals (problems with the method of requesting psychologist cooperation and problems of consultation and liaison work within the hospital)', 'Specialized support provided by psychologists (difficulty of interaction with patients and their families, inadequate provision of psychological support in cancer care, problems related to death care and lack of psychiatric knowledge)', 'Stress faced by psychologists (psychologist's isolation and anxiety, psychologist's internal conflicts, psychologist burnout and helplessness and psychologist self-improvement)'.

Conclusions: Psychologists must acquire at least a minimal level of medical knowledge and understanding of cancer treatment. Furthermore, they require training through specific case studies in order to facilitate collaboration with other medical professionals and concrete training in aspects of psychological support that are specifically tailored to cancer treatment through case studies.

Key words: $psychologist - cancer\ care - trouble - hardship - education$

INTRODUCTION

The Basic Plan for Cancer Control Measures of 2009 emphasizes the alleviation of physical symptoms and provision of support for psychological problems from the early stages of treatment. In addition, providing appropriate support, including emotional care, to both cancer patients and their families

is also highly valued. Thus, in the future, psychologists, along with psycho-oncologists are expected to increasingly contribute to cancer care and palliative care. Iwamitsu et al. (1) conducted focus group interviews of physicians and nurses about the roles of psychologists in palliative medicine; in particular, the roles demanded by the palliative care

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team were a major focus. They found that psychologists are expected to communicate with other medical professionals based on their broad knowledge of cancer treatment and utilize their expertise in psychology to provide psychological support to patients and family members, as well as other medical professionals. Unfortunately, the number of psychologists who can actually perform these functions is limited, and this is becoming a challenge for psychologists in cancer care, in Japan.

Meanwhile, following specific recommendations by the National Council for Hospice and Specialist Palliative Care Services (2) to include a psychologist as a member of the hospital palliative care team, psychologist involvement is slowly increasing in Western countries (3). In many Western countries, particularly in the UK, the role of psychologists has developed as one of assessment, therapy and consulting, within their relatively new post in the hospice setting (4). Consequently, having a psychologist as part of the multidisciplinary team has enhanced the psychological component of palliative care within the hospice setting. This is not surprising, given that psychologists in the UK must complete academic and professional training (5). Psychologists in countries such as Sweden, Australia, Korea and China are certified by the national government, while psychologists with Ph.D. degrees and intern training experience in the USA are certified by each state (6,7). However, Japanese psychologists are not certified by the national government, and they receive only 2 years of post-baccalaureate education, which is much shorter than that required in other countries. They undergo a multidisciplinary, cross-sectional certification process first pioneered primarily in the field of education. For this reason, psychologists working not just in cancer treatment, but across multiple fields of medical treatment, are in a precarious position. Among them are many psychologists working in the field of mental health, where the demands are high. Physicians have indicated problems with awareness, expertise and educational background of psychologists, including the lack of knowledge of medical science and treatment (8-10).

Quite a few psychologists working in cancer care are unsure about their own roles. Furthermore, many psychologists involved in cancer care have not fully mastered the knowledge and skills of the field. According to Kodama et al. (11), ~70% of psychologists in cancer care are unsatisfied with limited training opportunities in/out of their hospitals, and ~80% are not supervised by faculty of certified graduate schools on clinical psychology. The education system for cancer care psychologists remains inadequate, and thus psychologists working in these circumstances are thought to face numerous difficulties. In June 2012, the Japanese Ministry of Health, Welfare and Labour emphasized the importance of education for psychologists in cancer and palliative care with the basic plan to promote cancer control programs. However, a few studies have examined psychologist troubles and hardships in the cancer care setting, and little qualitative and systematic studies exist on education programs for cancer care psychologists.

Given the above, we conducted a questionnaire survey of psychologists involved in cancer care and palliative care. We analyzed specific responses about troubles and hardships actually faced by psychologists working in cancer care, with the aim to identify problems experienced by psychologists involved in cancer and palliative care and consider an education system for psychologists.

PARTICIPANTS AND METHODS

PARTICIPANTS

Subjects were cancer care psychologists at a total of 1185 facilities as of June 2009 (the time the research was conducted). These included 315 cancer center hospitals and 834 other designated clinical teaching hospitals and university hospitals. Because it is not possible to identify the above psychologists specifically, we used a double-envelope system. Briefly, we sent one copy of the questionnaire form for facility representatives, a request for participation in the study, and an explanation of the study to representatives of the 1185 facilities. We also mailed five copies of the questionnaire form to psychologists involved in cancer care, a request for participation in the study, and an explanation of the study to psychologists.

First, we asked the institution representatives to note (on the questionnaire form for facility representatives) the affiliation and number of psychologists working at the facility, and the number and area of affiliation of psychologists to whom the psychologist questionnaire was actually distributed. Of the total of 1185 facilities, 403 facilities responded (response rate: 34%). Among the 403 facilities, 136 employed no psychologists, and 267 employed psychologists, of which 326 were full-time and 164 were part-time psychologists, for a total of 490 psychologists.

Furthermore, at these 267 facilities, 419 psychologists thought to be involved in cancer care were actually given the questionnaire. Psychologists who received the questionnaire were asked to fill it out anonymously and return it. The study was explained in writing to representatives and psychologists involved in cancer care, and replies were regarded as consent to participate. Of the 419 given the questionnaire, 401 psychologists replied (response rate: 95.7%). We analyzed the data received from these 401 psychologists (89 male, 310 female, 2 unspecified; average age 37.2 ± 9.5).

This study was approved by the ethics committee of the Kitasato University School of Medicine.

QUESTIONNAIRE

The questionnaire targeting psychologists involved in cancer care was designed according to a literature review and exchanges of opinion with psychologists with 5 or more years of experience in cancer care, professionals with experience in psycho-oncology and researchers. The questionnaire was divided into five main areas:

- (i) Basic attributes: included questions about sex, age, educational background, years of clinical experience, current workplace, whether or not workplace has psychologists or psychiatrists, clinical psychology qualifications, annual income, etc.
- (ii) Knowledge and skills related to the field of cancer care: subjects were asked to rate on a scale of 1-4, the degree of necessity for psychologists for 28 items.
- (iii) Work duties related to cancer: subjects were asked to rate on a scale of 1-4, the degree that 22 items were demanded in the workplace.
- (iv) Working conditions related to cancer care at present workplace: subjects were asked what percentage of their work duties in the past year were related to cancer care, the total number of cases, the subjects of care and breakdown of the types of work.
- (v) Problems confronting psychologists working in cancer care: subjects were asked to write freely about troubles or hardships they experienced while working in cancer care.

We analyzed troubles and hardships experienced by psychologists working in cancer care based on their responses to questionnaire areas 1 ('basic attributes') and 5 ('problems confronting psychologists working in cancer care').

PROCEDURES

Participants were asked to fill out the questionnaire voluntarily following the written explanation. The returned questionnaire within 2 weeks was regarded as consent.

OVERVIEW OF ANALYSIS

In order to investigate the potential differences in basic attributes between those who filled out the free response section about troubles or hardships actually experienced while working in cancer care (hereafter, 'free response group') and those who did not (hereafter, 'no-response group'), we divided respondents into two groups, calculated the average \pm SD of age and years of clinical experience for each group, and performed a t-test. Next, to examine whether the existence of free responses were affected by sex (male or female), form of employment (part- or full-time), existence of a palliative team (yes or no) and participation in the palliative team (yes or no), the χ^2 test was performed for each of these factors.

We performed qualitative content analysis of free responses about troubles or hardships actually experienced while working in cancer care by referencing methods used by Mayring (12). First, two of the five analysts each extracted the key expressions and content from the responses of 192 psychologists. Next, names (code names) were attached to expressions and content, and similar contents were coded. Based on this, similar codes were aggregated and categorized, and category names were given. Finally, two analysts and one researcher in psychology and two

psychologists checked and discussed the codes and categories repeatedly until an agreement was reached, and content validity was examined.

RESULTS

BASIC ATTRIBUTES IN PARTICIPANTS

On the question of troubles or hardships actually experienced while working in cancer care, there were 107 people in the no-response group (28 male, 77 female, average age \pm SD: 39.4 ± 9.5) and 294 people in the response group (61 male, 233 female, average age \pm SD: 36.3 \pm 9.4). Average number of years of clinical experience \pm SD was 13.1 \pm 10.1 in the no-response group and 10.2 ± 8.8 in the free response group. An average number of years of medical experience ± SD were 11.2 ± 9.6 in the no-response group and 9.1 ± 8.5 in the free response group. An average number of years in cancer care \pm SD was 3.4 \pm 4.3 in the no-response group and 3.1 \pm 3.3 in the free response group. The t-test found no difference between the two groups with regard to these attributes. The χ^2 test was performed for sex as well between free response (no-response group and free response group) and sex (male, female), but no bias in incidence was found. The χ^2 test performed for free response (no-response group and free response group) and form of employment (part-time, full-time) found that there were 75 full-time psychologists and 30 part-time psychologists in the no-response group, and 213 full-time psychologists and 74 part-time psychologists in the free response group, but no bias between them in the incidence. In the no-response group, 76 psychologists had a palliative team and 27 did not. In the free response group, 265 psychologists had a palliative team and 25 did not. The χ^2 test results to examine the presence of responses (no-response group, free response group) and presence of a palliative team (no team group, team group) revealed a bias in the incidence. In the free response group, the incidence of workplaces with palliative care teams was high at roughly 90%, while the no-response group showed a low incidence of workplaces with palliative care teams, at slightly >70% (P < 0.05). Similarly, for participation in the palliative care team, the no-response group had 46 people who had not participated in a palliative care team, while 57 had. On the other hand, in the free response group, 77 people had not participated in a palliative care team, while 211 had. The χ^2 test performed for responses (no-response group, free response group) and palliative team participation (no participation group, participation group) revealed a bias in the incidence. While participation in a palliative care team was >70% in the free response group, that in the no-response group palliative care team was <50% (P < 0.05).

TROUBLES AND HARDSHIPS

The following five categories were obtained in qualitative analysis of the free responses: 'Hospital system',

Table 1. Hospital system

Subcategory	Examination					
Problems related to the hospital organization	The hospital organization is not large enough, lack of manpower					
	Poor hospital management					
	Lack of recognition of team medicine					
	No full-time psychiatrist					
	No appropriate department to which psychologists can belong					
Psychologist working arrangements	Psychologists cannot work properly due to the part-time status					
	Work limitations because only one psychologist works there					
	Preoccupation with work duties other than cancer care					
	Lack of economic independence					

'Psychologist role and specialization', 'Collaboration with other medical professionals', 'Specialized support provided by psychologists' and 'Stress faced by psychologists'.

In the 'Hospital system' category, the following two subcategories were extracted: (i) hospital or organization problems and (ii) problems with working arrangements (Table 1).

In the second category 'Psychologist role and specialization', three subcategories were extracted: (i) ambiguity of the role expected of psychologists, (ii) problems arising because psychologists are not nationally licensed and (iii) lack of clarity regarding psychologist specialization (Table 2).

In the third category 'Collaboration with other medical professionals', four subcategories were extracted: (i) problems with the method of requesting psychologist cooperation, (ii) problems related to the palliative care team, (iii) problems of consultation and liaison work within the hospital and (iv) problems of communication between medical staffs (Table 3).

In the fourth category 'Specialized support provided by psychologists', five subcategories were extracted: (i) difficulty of interaction with patients and their families, (ii) inadequate provision of psychological support in cancer care, (iii) problems related to death care, (iv) lack of medical knowledge and (v) lack of psychiatric knowledge (Table 4).

In the last category 'Stress faced by psychologists', four subcategories were extracted: (i) psychologist isolation and anxiety, (ii) psychologist internal conflicts, (iii) psychologist burnout and helplessness and (iv) psychologist self-improvement (Table 5).

DISCUSSION

We extracted the following five categories from qualitative analysis of the difficulties faced by psychologists: 'Hospital

Table 2. Psychologist role and specialization

Subcategory	Examination					
Ambiguity of the role expected of psychologists	Other medical professionals do not understand the psychologist's specialty					
	Other medical professionals have different expectations for the roles played by psychologists					
	Other medical professionals expect psychologists to play the same role of psychiatrists					
	Other medical professionals have excessive expectations of psychologists					
Problems arising because psychologists are not nationally licensed	Work performed by psychologists is limited because it is not covered by the medical insurance system					
	Inconsistent treatment of psychologists					
Lack of clarity regarding psychologist specialization	Other medical professionals do not understand psychologist specialization in cancer treatment					
	Psychologists do not know how to make other medical professionals understand their specialization					
	Psychologist's work overlaps with nurses' work duties in some cases					
	Difficulty of having psychologist's activities and results evaluated by other medical professionals					

system', 'Psychologist role and specialization', 'Collaboration with other medical professionals', 'Specialized support provided by psychologists' and 'Stress faced by psychologists'. We will discuss each of these categories and examine an educational program for psychologists aimed at addressing these issues.

First, the 'Hospital system' category includes subcategories encompassing difficulties associated with 'problems related to the hospital organization' (e.g. lack of manpower and a full-time psychiatrist position), and 'psychologist working arrangements' (e.g. psychologists cannot work properly due to the part-time status). In the 'Psychologist role and specialization' category, subcategories include the 'ambiguity of the role expected of psychologists', as other medical professionals do not understand or have different expectations for the roles played by psychologists; 'problems arising because psychologist are not nationally licensed', leading to the inconsistent manner in which psychologists are treated and 'the lack of clarity regarding psychologist specialization' because other medical professionals do not understand psychologist specialization in cancer treatment, or psychologists do not know how to make other medical professionals understand their specialization. In examining the causes of these problems, the lack of certification by the

Table 3. Collaboration with other medical professionals

Subcategory	Examination					
Problems with the method of	Few requests for psychologists					
requesting psychologist cooperation	Other medical professionals turn to psychologists only after the patient's physical symptoms and psychological condition worsen					
Problems related to the palliative care team	Insufficient communication within to palliative care team					
	The palliative care team is not active enough					
	Inability to function as a psychologi within the palliative care team					
	Inability to cooperate smoothly with nurses					
Problems of consultation and liaison work within the hospital	A lack of adequate communication with professionals of other medical professionals					
	Trouble relating to other ward staff					
	Professionals of other job types do not fully understand the psychologist's position and role					
	I cannot smoothly provide information to patients due to inadequate skills of the psychologist					
	Insufficient relations to psychiatrist					
Communication problems between other medical professionals	Lack of communication between medical practitioners other than psychologist					

national government has previously been identified as a contributing factor, alongside other weaknesses in the psychology education system (13). Due to the lack of state certification, psychologists participating in medical treatment are not fully covered by the medical insurance remuneration system (14). Consequently, psychologists working in the medical field are often left in a precarious position. It is likely that this lack of national certification also adds to the difficulty of other medical professionals understanding the area in which psychologists specialize. In fact, psychologists in countries such as Sweden, Australia, Korea and China are certified by the national government, while psychologists with Ph.D. degrees and intern training experience in the USA are certified by each state (6,7). Although these issues cannot be resolved immediately in Japan, we propose that a gradual resolution can be reached by clarifying the role psychologists play in medical treatment, particularly in cancer treatment. Furthermore, it was found that psychologists do not adequately understand their own area of specialization. In the present study, the average number of years (\pm SD) of clinical experience and medical experience in the free response group was 10.2 (\pm 8.8) and 9.1 (\pm 8.5), respectively, but the average number of years in cancer care was shorter, with 3.1 (\pm 3.3). Holland (15) reported that psychologists,

Table 4. Specialized support provided by psychologists

Subcategory	Examination					
Difficulty of interaction with patients and their families	Difficulty of handling patient/family aggression and dissatisfaction					
	Struggles with resistance by patient/family toward interviews					
	Difficulty interacting with patients suffering from severe physical pain					
Inadequate provision of psychological support in cancer care	Difficulties in deciding how and when to provide this care					
	Difficulties in setting the objectives an goals of psychological intervention					
	Little knowledge about psychological changes in cancer patients					
Problems related to death care	Mental shock towards patient death, inadequate death care					
Lack of medical knowledge	Do not know how to enter information on medical charts					
	Do not understand medical terminolog					
	Do not understand cancer treatment					
Lack of psychiatric knowledge	Insufficient knowledge about drug therapy					
	Insufficient knowledge about psychiatric symptoms					
	I cannot perform assessment of psychiatric symptoms					

traditionally trained to play a central role in the treatment of physically healthy individuals with psychological problems, faced the lack of a well-defined role in cancer care due to the absence of psychologically oriented peers, and a sense that 'one is an outsider working in someone else's specialty'. We think that psychologists who have less experience in cancer care confront similar situations in Japan. The 2012 Basic Plan for Cancer Control Measures states that psychooncologists and psychologists in cancer care should systematically receive education to provide psychological support for cancer patients and their families; however, no education system for psychologists in cancer care has yet been established in Japan. Furthermore, few studies have investigated the role of psychologists in hospices in Japan. Thus, the role and specialization of psychologist in cancer care is still unclear in Japan. In these scenarios, psychologists cannot expect other medical professionals to fully understand their field. This point also relates to the category of 'Psychologist's role and specialization' and 'Specialized support provided by psychologists', suggesting that specialized support provided by psychologists should be more firmly defined.

The 'Collaboration with other medical professionals' category includes four subcategories. The first subcategory concerns the 'problems with the method of requesting psychologist cooperation'. These problems arise because other medical

Table 5. Stress faced by psychologists

Subcategory	Examination
Psychologist's isolation and anxiety	An absence of people with whom the psychologist can consult at the workplace
	Discharging tasks alone put great strain on psychologists
	Insufficient support from professionals of other medical professionals
	Lack of complete confidence in duties performed as psychologist, no evidence for psychological treatment
Psychologist's internal conflicts	I cannot follow-up on patients who change hospitals or are discharged
	Struggle with aggression or dissatisfaction from patients
	I am unable to meet the demands of other medical professionals
Psychologist burnout and helplessness	I feel powerless and unrecognized by other medical professionals
	I feel powerless due to the inability to do anything for suffering patients
Psychologist self-improvement	Demand for study and training groups to be held in rural areas
	Demand for lectures tailored to participant's level (i.e. beginner or advanced)
	Demand to explore case studies in the cancer field
	Demand for a supervisor in cancer care and a place for psychologists to share information
	Demand for more reference materials about the role of psychologists in cancer care

professionals turn to psychologists only after the patient's physical symptoms and psychological condition worsen. The second subcategory includes 'problems related to the palliative care team' (e.g. problems due to insufficient communication within the palliative care team), and the third, the 'problems of consultation and liaison work within the hospital', which result from a lack of adequate communication with other medical professionals. The fourth category encompasses the 'problems of communication between other medical professionals', including the lack of communication between non-psychologist medical professionals. When considering communication problems in the medical treatment, the first issue is that psychologists must know a common language if communication is to be possible (16). Furthermore, psychologists' lack of medical knowledge has previously been identified by many physicians as contributing to problems in communication (9,10). An understanding of the content of other medical professionals' conversations and what they record in medical charts is necessary for communication between medical professionals in the medical field. In other words, psychologists should understand the specialization of other medical professionals, just as other medical professionals should understand the specialization of psychologists. Efforts to communicate with one another will lead to active and appropriate referrals to psychologists. Belar et al. (17) proposed that psychologists in the USA need to collaborate with other medical professionals in hospitals and must be knowledgeable regarding formal and informal medical cultures, norms, mores and practices in health-care settings. Similarly, we feel it necessary for psychologists in cancer care to gain the support of other medical professionals in order to acquire these skills and knowledge. To this end, psychologists should attend and actively participate in case conferences with other medical professionals. Other medical professionals should support their joining. There are also adverse effects that occur when psychologists insist on staying within the unique framework of psychology. For example, other medical professionals on palliative care teams have reported a problem in information sharing among psychologists working in cancer treatment, as they tend to keep information and cases to themselves (1). This may foster an image of psychologists as a secretive or solitary worker.

Matusno (18) has proposed the following five explanations for why psychologists cannot function effectively in the field of medical treatment, particularly in team-based medicine: (i) their lack of clinical experience in hospitals; (ii) their lack of basic medical education; (iii) their lack of being viewed as providers of therapy in the context of medical treatment; (iv) their lack of experience in team-based treatment and (v) their lack of knowledge on psychological techniques necessary in hospitals. The subcategories of problems listed under 'Collaboration with other medical professionals' are also linked to the points raised by Matusno (18). For these reasons, psychologists must acquire at least a minimal level of medical knowledge and understanding of cancer treatment. Furthermore, they require training through specific case studies in order to facilitate collaboration with other medical professionals.

In the 'Specialized support provided by psychologists' category, subcategories included the following: 'difficulty of interaction with patients and their families', which relates to how psychologists deal with emotions of aggression and dissatisfaction in patients and family members, as well as how they interact with patients suffering from severe physical pain; 'inadequate provision of psychological support in cancer care' (e.g. difficulties in setting the objectives and goals of psychological intervention, deciding how and when to provide this care); 'problems related to death care'; 'the lack of medical knowledge' and 'the lack of psychiatric knowledge'. The last two subcategories are related to the previously cited problems in collaboration with other medical professionals, but these issues are also fundamental in the specialized support that psychologists provide. Acquiring basic knowledge on medicine, cancer treatment and psychiatry is a necessary precondition for psychologists working in cancer treatment and is the major foundation of education programs for psychologists in cancer medicine (1).

On the other hand, the 'difficulty of interaction with patients and family', 'inadequate provision of psychological

and anxiety' for not having people to consult with at the

workplace or receiving insufficient support from other medical professionals; 'psychologist's internal conflicts'

(e.g. psychologists cannot be involved in the care of many

patients, or are unable to meet the demands of other medical professionals); 'psychologist burnout and helplessness' (e.g.

the powerless feeling of psychologists unrecognized by other professionals) and 'psychologist self-improvement' (e.g. the desire to explore case studies in the cancer field, desire for an increase in the number of study and training groups or for a place to share information among psychologists). The 'psychologist's isolation and anxiety' and 'psychologist burnout and helplessness' subcategories are connected to the 'lack of clarity about the role psychologists are expected to play' and 'lack of clarity regarding the psychologist's specialization' mentioned above. We think that these issues emerge because psychologists' area of specialization in medical treatment is often unclear, leading to a lack of understanding from other medical professionals. Rieger et al. (22) suggested that a cohesive team approach entailing mutual respect and support between other medical professionals would mitigate the difficulties experienced by psychologists. In Japan, some psychologists feel isolation and anxiety, and do not have other psychologists to consult with at workplace; therefore, it is essential that other medical professionals communicate actively and try to understand the specialization of psychologists, or try to support them. On the other hand, professional networking among psychologists in cancer care is less mature than in other medical fields with highly advanced technology (11), and 40% of psychologists in cancer care do not have seniors and associates in the field to consult with. Finally, we found that psychologists feel a need to engage in selfimprovement activities, as reflected in the desire to receive more opportunities for learning and training, supervision and/or peer review on the regular basis. Although recognized standards for education and training in clinical health psychology exist for those new to the field, the needs of psychologists already in the field who wish to develop more expertise in selected areas of practice have not been sufficiently addressed in the USA (17,23). In Japan, however, recognized standards do not exist even for those at the entry level of practice. Belar et al. (17) proposed that psychologists in heath psychology including cancer care should self-assess their readiness to provide psychological professional services before working in health psychology (17). Along these lines, the National Cancer Institute and American Cancer Society websites provide information for self-assessing the readiness to deliver services to women with breast cancer. While a realistic option for a basic education program in Japan may involve creating an environment in which psychologists

There are some limitations to this study worth noting. First, we identified categories that represent troubles and hardships experienced by psychologist working in cancer

comprehensive education programs is also essential.

can study via E-learning based on their individual needs, the

development of sorely needed systematic, sequential and

support in cancer care' and 'problems related to death care' are specific to the psychological support provided in cancer treatment. Furthermore, psychologists involved in cancer treatment feel that, because it is difficult to establish a framework for psychological interviews, there are major difficulties in establishing a psychological support method that flexibly responds to individual situations. In reality, there is very little training for psychologists specific to cancer treatment, and this field is rarely studied in graduate school (19). Recently, however, patients and family members have been using the Internet and books to acquire fairly detailed knowledge about their disease and treatment. The mental state of cancer patients changes as a result of physical condition, therapeutic course and treatment side effects. For these reasons, psychologists involved in cancer treatment must acquire knowledge about cancer treatment that they can then apply when providing psychological support (1). Furthermore, by acquiring psychiatric knowledge, the psychologist can begin to provide specialized psychological support. If psychologists are not able to flexibly provide patients and family members with psychological support while taking into consideration their physical state, the extent to which they have been informed about their illness, the state of their therapy, their personal character, their family composition, etc., it will be difficult to improve the cancer specialization field within psychology (20). According to Payne and Haynes (5), psychologists in palliative care are applied scientists, who are trained to work with individuals, couples and families, and provide a consultative service to healthcare staff, as well as bring a unique perspective to the assessment and treatment of patients. In the UK, all psychologists complete both academic and professional training, drawing on the knowledge of a wide range of psychological theories to explain and understand the cognitive, emotional and behavioral aspects of responses to illnessrelated issues. Some theories include specific psychological intervention, such as adjuvant psychological therapy for cancer patients (21). Psychologists with Ph.D. degrees in the USA experience intern training (6). In Japan, however, psychologists are trained in a university graduate school through poor educational curriculums in cancer care, etc., and are thus not fully prepared. In this regard, we think that concrete training through case studies in aspects of psychological support specifically tailored to cancer treatment would provide the foundation of educational programs for psychologists in cancer treatment in Japan. In other words, psychologists in Japan should acquire appropriate skills to provide psychological intervention suitable for cancer patient, as well as to offer accurate assessment of the mental state of cancer patients. To this end, the construction of an educational program geared toward improving psychologists' level of experience on a case-by-case basis will be necessary (e.g. clinical experience in medical treatment or in cancer treatment).

The last category, 'Stress faced by psychologists', includes the following four subcategories: 'psychologist's isolation care, but did not go further to examine what psychologists find challenging, or to what extent. In the future, we plan to perform quantitative analysis of the degree of challenges faced by psychologists based on the results of this study. Secondly, although we describe the employment status of psychologists and their participation in a palliative care team, no investigation was performed in the present study to address these points. Thus, the future study should focus on these points, as well as other factors such as psychologist personality, experience and mental state.

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Conflict of interest statement

None declared.

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Original Article

Problem-Solving Therapy for Psychological Distress in Japanese Early-stage Breast Cancer Patients

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Objective: The current report provides the result of a Phase II clinical trial regarding the effectiveness and feasibility of problem-solving therapy for psychological distress experienced by Japanese early-stage breast cancer patients.

Methods: Participants were 36 post-surgery Japanese breast cancer patients in a university hospital located in Osaka Prefecture, Japan. After screening for psychological distress using the Distress and Impact Thermometer and the Hospital Anxiety and Depression Scale, highly distressed patients were exposed to 5 weekly sessions of the problem-solving therapy program.

Results: Nineteen patients completed the intervention and follow-up. There was a significant difference between the pre-intervention and the 3-month follow-up in the total Hospital Anxiety and Depression Scale score (P = 0.02), and the mean change score from the pre-intervention to the follow-up was 6.05 (SD = 1.94). The intervention had a large effect size (d = 0.82). There were also significant changes in worry, self-efficacy and quality of life measures.

Conclusions: The findings of our study suggest that the problem-solving therapy program has potential to be effective for alleviating psychological distress experienced by Japanese early-stage breast cancer patients. The true effectiveness of the program should be confirmed by a future randomized control trial.

Key words: cancer - psychological distress - problem-solving therapy - psychological intervention

INTRODUCTION

The experience of cancer causes considerable stress to patients. Previous studies investigating the prevalence of psychological distress in cancer patients have revealed rates of 15-40% (1). In addition, some patients seek psychological help even though their psychological status does not reach a formal psychiatric diagnosis (2). In particular, psychological distress is a significant problem for breast cancer patients. Approximately 20-40% of women with breast cancer

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reported clinically significant levels of depression during or after treatment (3–5). Protracted breast cancer treatment and inadequate psychological adjustment after breast surgery, adjuvant chemotherapy or radiation therapy may cause patients to face difficulties in daily life, work, human relationships and adherence to hormone therapy. Therefore, psychological support at this phase is important for patients' quality of life (QOL).

Two therapies for psychological distress considered to be potentially effective are psychotherapy and pharmacotherapy. Regarding patient preference, a Japanese study indicated that psychotherapy is more acceptable than pharmacotherapy among cancer patients (6). Although previous reviews highlight the general efficacy of various psychosocial interventions, very few studies addressed what kind of psychotherapy is feasible or effective for Japanese cancer patients in actual breast cancer treatment settings.

Therefore, we have been interested in the effectiveness and feasibility of problem-solving therapy (PST) as a brief, structured psychological intervention. PST is one form of cognitive-behavioral therapy based on social problem-solving theory (7) and includes five components: (i) problem definition, (ii) goal setting, (iii) solution generation, (iv) decision-making, (v) implementation. In the Western literature, PST for depression (8) or other mental and physical health problems (9) has been demonstrated to be effective via meta-analysis. Especially in the realm of oncology, PST programs for cancer patients with their significant others (10) and including mothers for pediatric cancer patients (11) have been developed and validated as useful strategies.

We have previously reported clinical findings using our early version of PST programs for Japanese cancer patients in which the feasibility and effectiveness of PST have been suggested (12). The current report introduces a Phase II clinical trial demonstrating the feasibility and effectiveness of PST for psychological distress experienced by Japanese breast cancer patients after surgery.

PATIENTS AND METHODS

PARTICIPANTS

We conveniently enrolled 36 post-surgery Japanese breast cancer patients from seven physicians of a university hospital located in Osaka Prefecture, Japan in our study from November 2008 to August 2010. The inclusion criteria were (i) patients who were diagnosed as having breast cancer either clinically, histologically or pathologically; (ii) patients who had received adjuvant chemotherapy 6 months after surgery or who had received only hormone therapy after surgery; (iii) patients who had been told their diagnosis; (iv) patients aged older than 20 years and younger than 70 years; (v) patients with Eastern Cooperative Oncology Group (ECOG) PS being 0 or 1, and having the ability to go to the

hospital and to work with light physical activity; (vi) patients who had met the criteria for one of their scores on the Distress and Impact Thermometer (DIT) or the Hospital Anxiety and Depression Scale (HADS) (see *measures*, *P.7*). To ensure a sufficient sensitivity for patients who experienced psychological distress, we adopted the sixth condition.

The exclusion criteria were (i) patients who were diagnosed by a physician as requiring psychiatric treatment, such as patients suffering from depressive disorder with suicidal thoughts or wishes; (ii) patients with the evidence of cognitive impairment such as dementia and delirium or mental illness such as schizophrenia; (iii) patients taking antipsychotics; (iv) patients with the evidence of cognitive function impairment; (v) patients with difficulties in Japanese language literacy.

PST PROGRAM

The intervention program was an individual psychological treatment based on PST. According to the principles behind PST (13,14), psychosocial problems influence psychological distress (e.g. depression, anxiety). Therefore, it is useful to teach structured problem-solving strategies to patients. We developed a PST program for Japanese cancer patients, modeling the concepts and techniques of PST used in previous western studies (10,14). This program included a therapist manual and a worksheet for patients (all materials are available from the authors). Our PST program consisted of 5 weekly sessions (1 h/session) and was conducted according to a worksheet developed using five steps for problem solving: Step 1: assessing their problems; Step 2: setting an achievable goal related to one of their problems; Step 3: generating a solution; Step 4: choosing the solution; Step 5: implementing the solution and evaluating the outcome.

PROCEDURE

This study utilized a before and after design. The study protocol was approved by the institutional review boards of the Osaka University Hospital and was registered in the clinical trials registry by the University Hospital Medical Information Network (UMIN-CTR). First, physicians of the eligible patients informed the patients about the aim of the study during an outpatient adjuvant chemotherapy or hormone therapy session. Then, research staff conducted a psychological screening of patients using DIT and HADS. If patients met the inclusion criteria and consented to enroll in this study via written consent, the PST program was started. Self-reported questionnaires were conducted before the first session (pre-intervention), after the final session (postintervention) and 3 months after the final session (3-month follow-up). To confirm the feasibility of the intervention, telephone interviews were also conducted on the follow-up or when the participants turned down the continuation of the intervention (dropout) to explore the qualitative aspects of the intervention.

MEASURES

Demographic data such as sex, age and educational level were obtained by self-report. Medical information was obtained from patients' doctors. Five psychological and QOL measures were utilized as follows:

- (i) The DIT (15) is a two-item self-reported questionnaire for assessing patients' psychological distress on an 11-point Likert-type scale, ranging from 0 (not at all) to 10 (extremely). Although the standard cut-off score for screening for adjustment disorder and major depression is 3/4 on the 'distress' score and 2/3 on the 'impact' score, in this study, we employed an inclusion criterion of a distress score cut-off of 2/3 and an impact score cut-off of 0/1 in order to ensure a sufficient sensitivity to psychological distress.
- (ii) The Japanese version of the HADS (16) was used for evaluating depression and anxiety. It consisted of 14 items (7 items each for anxiety and depression), and participants rated how they felt during the previous week on a 4-point scale. Total scores ranged from 0 to 42. The cut-off score for screening for adjustment disorder and major depressive disorder among the Japanese cancer patients was 10/11 (17). Thus, in this study, we used this score (10/11) as the inclusion criterion.
- (iii) The Self-Efficacy for Advanced Cancer (SEAC) (18) was used to assess the degree of self-efficacy in the patients. It is an 18-item scale on an 11-point Likert-type scale, ranging from 0 (not at all confident) to 100 (extremely confident). The SEAC consisted of the following three subscales: symptom coping efficacy (SCE); activities of daily living (ADL) efficacy (ADE) and affect regulation efficacy. Higher aggregate scores on each subscale indicate a greater level of self-efficacy for symptom coping, ADL and affect regulation.
- (iv) The Brief Cancer-related Worry Inventory (BCWI) (19) was used to measure the contents and intensity of patients' worry. Participants were asked to rate their degree of worry across 15 items on an 11-point scale, ranging from 0 (not at all worried) to 100 (extremely worried). The BCWI consisted of subscales concerning future prospects (6 items), physical problems (4 items) and interpersonal problems (5 items). Higher aggregate scores indicated worrying about a greater variety of issues.
- (v) The Japanese version of the European Organization for Research and Treatment of Cancer 30-item Core Quality of Life Questionnaire (EORTC QLQ-C30) (20) was used to measure QOL. In this study, we measured the global health status score in addition to physical, role, cognitive, emotional and social function.

SAMPLE SIZE CALCULATION AND DATA ANALYSIS

We first calculated the natural change in HADS score in the Japanese breast cancer patients after surgery using data from a previous observational study (21). Patients with a high HADS score (11) 3 months after surgery and without adjuvant chemotherapy displayed a gradual increase in HADS score from 3 months (15.81 \pm 4.21) to 6 months (17.55 \pm 5.66), and the mean change in HADS score was 1.74 \pm 6.82. The mean minus 1 SD (|1.74 - 6.82| = 5.08) could possibly represent a clinically significant change by the intervention. That is, we assume that this mean HADS change score represents a natural change and that a 5-point decrease in HADS score over 3 months could represent a clinically significant improvement by the intervention.

We calculated the sample size using this decreased HADS score (5.0) as the estimated effect size of the intervention and 6.0 as the standard deviation in HADS score among distressed patients (HADS score 11 and without chemotherapy). In the end, we found that the required sample size for this study was 17 ($\alpha = 0.05$, $\beta = 0.10$). However, in order to obtain the needed number of patients for the analysis, we had decided that 30 patients should be enrolled in this study, due to the potential elimination or dropout of patients during the trial.

We conducted all statistical analyses using the SPSS software package (version 19.0). Descriptive statistics were calculated as an average of all measures at each time point (pre-, post- and follow-up tests). In order to investigate the effectiveness of the intervention, we conducted three separate repeated-measures ANOVAs for HADS, BCWI, SEAC and EORTC-QLQ scores.

RESULTS

Of the 36 participants targeted, 26 individuals agreed to enroll in this study. Of the 26 patients, 3 were not eligible under our inclusion criteria, 3 dropped out after starting treatment (they also did not respond to the final questionnaires) and 1 did not respond to questionnaires at the 3-month follow-up (see Fig. 1). The reasons for patients dropping out (n=3) was that it was difficult for 2 of them to participate in weekly sessions and it was a burden for 1 patient to think about her own problems. Therefore, in the end we analyzed 19 patients. Their mean age was 50.21 (SD = 11.09) years. The majority of the participants were married (n=15, 78.95%) and diagnosed with stage II cancer (n=18, 94.74%). Patients' characteristics are shown in Table 1.

PRIMARY OUTCOME MEASURE

The completion rate of the intervention was 82.6% (19/23). Table 2 presents the mean HADS scores and the other self-reported measures at the pre- and post-intervention and the 3-month follow-up stages. The mean change score from the

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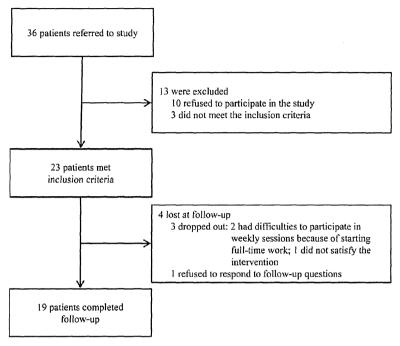


Figure 1. Trial profile in this study.

pre-intervention to the follow-up was 6.05 (SD = 1.94), which was above the previously assumed significant decrease (5.0). Repeated-measures ANOVA revealed a significant effect of time on total [F(2, 36) = 6.45, P < 0.01], anxiety [F(2, 36) = 5.56, P < 0.01], and depression scores [F(2, 36) = 5.55, P < 0.01]. A post hoc analysis with the Bonferroni method showed a marginally significant difference between the pre- and post-intervention in the total HADS score (P = 0.07, d = 0.47) and depression score (P = 0.07, d = 0.46) and a significant difference between the pre-intervention and the 3-month follow-up in the total HADS score (P = 0.02, d = 0.82), depression score (P = 0.03, d = 0.90) and anxiety score (P = 0.02, d = 0.86).

SECONDARY OUTCOME MEASURE

For worry measured by BCWI, repeated-measures ANOVA revealed a significant effect of time on all subscales of BCWI [future: F(2, 36) = 4.30, P = 0.02; physical: F(2, 36) = 4.93, P = 0.01; interpersonal: F(2, 36) = 8.47, P < 0.01]. A post hoc analysis showed a significant difference between the pre- and post-intervention in future prospect (P < 0.05, d = 0.42) and between the pre-intervention and the 3-month follow-up in future prospect (P = 0.04, d = 0.46) and in physical (P < 0.01, d = 0.59) and interpersonal problems (P < 0.01, d = 0.35).

Regarding self-efficacy measured by SEAC, repeated-measures ANOVA showed a significant effect of time on affect regulation [F(2, 36) = 8.38, P < 0.01]. A post hoc

analysis revealed, in terms of affect regulation efficacy, a significant difference between the pre- and post-intervention (P < 0.01, d = 0.56) and between the pre-intervention and the 3-month follow-up (P = 0.02, d = 64).

Finally, repeated-measures ANOVA for EORTC QLQ-C30 revealed a significant effect of time on global health status [F(2, 36) = 4.87, P = 0.01], emotional function [F(2, 36) = 4.33, P = 0.02] and social function [F(2, 36) = 8.48, P < 0.01]. A post hoc analysis showed a significant difference between the pre- and post-intervention in social function (P = 0.01, d = 0.86) and between the pre-intervention and the 3-month follow-up in global health status (P = 0.04, d = 0.82) and in social function (P = 0.01, d = 0.79).

DISCUSSION

The findings of our study suggest that the PST program is feasible and have potential to be effective for alleviating psychological distress experienced by Japanese early-stage breast cancer patients. The completion rate of the intervention was high (82.6%) and only one patient dissatisfied or felt burden of the intervention and the mean HADS change score from the pre-intervention to the 3-month follow-up (6.05) is larger than the expected mean change score (5.0) estimated from a previous observational study. Further, the effect size (d = 0.82) of our PST program is large and considered clinically meaningful. Therefore, although our study

Table 1. Patients' characteristics

Variable	n	% of sample		
Education				
Junior high school	1	5.26		
High school	9	47.37		
Junior/vocational college	5	26.32		
College	4	21.05		
Marital status				
Married	15	78.95		
Single	2	10.53		
Divorced	2	10.53		
Separated	0	0.00		
Occupational status				
Full time work	7	36.84		
Part time work	1	5.26		
Not working	8	42.11		
Breast cancer stage				
I	1	5.26		
II	18	94.74		
Treatment				
Surgery				
Mastectomy	4	21.05		
Lumpectomy	15	78.95		
Chemotherapy	19	100.00		
Neo-adjuvant	12	63.16		
Radiotherapy	6	31.58		
Hormone therapy	17	89.47		

Note: n = 19, mean age = 50.21 (SD = 11.09) years.

design is one arm without a control group, the feasibility and effectiveness of our PST program seem to be adequate for clinical application.

The most important finding is that a minimal intervention (namely, a short-term psychological intervention with only five sessions) seems to be helpful for breast cancer patients who experience psychological distress after surgery and adjuvant chemotherapy. Prior to this study, we had identified the timing at which the intervention would have the most significant impact on the alleviation of psychological distress (21). We consider that our moderate, clinically meaningful effect size is due to the appropriateness of the timing of the intervention just after adjuvant chemotherapy, in addition to the inclusion criteria being set at the adequate level of psychological distress (a total HADS score >11).

A number of studies have investigated the effects of psychological intervention for cancer patients. A systematic western review of the effectiveness of psychosocial interventions for cancer patients recommended cognitive behavioral therapy (CBT) (22). In Japan, the effect of group

psychosocial interventions (23,24) and progressive muscle relaxation has also been investigated (25). However, conducting group psychosocial interventions in an actual clinical setting is often difficult. Our intervention had a considerable effect in an extremely realistic clinical setting, and was made with careful consideration of specific points of its implementation for individual patients. Although PST is one form of CBT, our PST seems to have a more moderate structure, flexibility and simplicity compared with traditional and comprehensive CBT. These features of our PST were suited to Japanese breast cancer patients since most cancer patients do not have an extreme distortion of cognition and traditional CBT interventions are often not appropriate for cancer patients (12).

Therefore, our results may provide several suggestions for the clinical implementation of psychological interventions for breast cancer patients. This therapy will work for treating the fear of recurrence and/or metastasis of the disease, which is the most common distress experienced by Japanese cancer patients (26), and unfortunately there are no standard interventions for alleviating this distress (27). In addition, one previous study indicated the usefulness of PST in distress among palliative care patients (28). These findings suggest that PST can be used for a broad range of psychological distress situations in clinical settings. At the present time, we are conducting group PST intervention programs for mixedstage cancer patients, in which patients with advanced cancer and metastasis or end-stage cancer patients are included. We have not observed any difficulties utilizing this PST intervention for such patients.

The final remarkable result is the improvement observed in the index indicating patients' social relationships, such as EORTC's social function and interpersonal problems of BCWI. This indicates that our PST program facilitated patients' daily, family or work-related behavior and activities, which may have led to decreased symptoms of depression and anxiety in the patients. This could suggest that the intervention's effect may possibly vitalize patient behavior in a social context, thus initiating a cognitive change. Future studies on mechanisms of how the PST program works for social aspects in the process of a patient's adjustment to cancer are needed.

This study has several limitations. The study design utilized a before and after study design without a control group. However, if a control group would be set in this study, two types of control groups should be included: one being a no-intervention group and the other being an intentional control group using traditional counseling. In the current Japanese medical health system, there are seldom any tools available for the psychological care for breast cancer patients. It is thus almost impossible to provide an intentional control represented by patients receiving traditional psychological care in our study. Therefore, we employed data related to our primary endpoint from a previous observational study (21) for sample size calculation and to set to the strictest standard the estimated significant decrease in HADS

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Table 2. Mean scores of pre- and post-intervention and the 3-month follow-up tests for all measures

	Pre-intervention		Post-intervention		3-month FU		F	S	Effect size (d)	
	M	SD	M	SD	М	SD			Pre - Post	Pre – FU
HADS										
Total	14.42	8.02	10.95	6.60	8.37	6.77	6.45	< 0.01	0.47	0.82
Anxiety	6.74	3.48	5.32	3.16	3.89	3.16	5.56	< 0.01	0.43	0.86
Depression	7.68	5.04	5.63	3.80	4.47	4.01	5.55	< 0.01	0.46	0.90
BCWI										
Future	62.28	26.08	51.23	26.94	48.86	32.01	4.30	0.02	0.42	0.46
Physical	63.42	29.32	53.03	31.53	44.74	33.91	4.93	0.01	0.34	0.59
Interpersonal	55.16	25.40	47.21	27.11	39.47	31.87	8.47	< 0.01	0.30	0.35
SEAC										
Symptom coping	55.26	20.92	62.59	22.29	62.11	23.27	2.90	0.07	0.34	0.31
Affect regulation	56.45	20.26	67.72	19.82	69.47	20.61	8.38	< 0.01	0.56	0.64
Activity of daily living	72.25	20.78	79.30	17.37	81.84	17.06	2.81	0.07	0.37	0.51
EORTC QLQ-C30										
Global health status	53.95	16.52	67.98	17.62	72.37	27.08	4.87	0.01	0.82	0.82
Physical function	74.74	18.00	82.11	12.58	80.70	15.22	3.23	0.05	0.48	0.36
Role function	69.30	23.74	78.95	19.12	81.58	23.50	2.56	0.09	0.45	0.52
Cognitive function	67.54	25.74	77.19	18.60	78.07	22.26	1.75	n.s.	0.43	0.44
Emotional function	64.91	20.52	76.75	13.20	76.32	18.27	4.33	0.02	0.69	0.67
Social function	57.89	31.12	80.70	20.98	79.82	23.95	8.48	< 0.01	0.86	0.79

Note. n = 19; M, mean; SD, standard deviation; FU, follow-up; HADS, the Hospital Anxiety and Depression Scale; BCWI, Brief Cancer-related Worry Inventory; SEAC, the Self-efficacy for Advanced Cancer; EORTC-QLQ-C30, European Organization for Research and Treatment of Cancer 30-item Core Quality of Life Questionnaire, effect size $(d) = (\text{mean}_{\text{pre}} - \text{mean}_{\text{post}} \text{ or FU})/\text{SD}_{\text{pooled}}$.

score following intervention. We believe that these procedures have contributed to the validity of our study, although the results will need to be interpreted in a certain limited way. The second limitation of our study is the sampling method. We used convenient sampling and could not use consecutive sampling because the initial recruitment for this study relied entirely on physicians in a very busy outpatient service. This may have resulted in systematic and random errors in the study. However, our strict inclusion criteria and selection process using psychological screening tools should have reduced systematic errors. The true effectiveness of the program should be confirmed by a future randomized control trial.

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Conflict of interest statement

None declared.

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時 評

「がん対策基本法」施行後5年を振り返る 一がん患者とその家族への心のケアの さらなる推進を願って一

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はじめに

がんは、昭和56年からわが国の死亡原因の第1位であり、わが国において2人に1人が生涯に一度はがんを罹患し、現在の死亡原因として3人に1人ががんにより亡くなっている。がんは加齢とともに発生しやすくなる疾患であり、高齢化が進むわが国では、今後もがん患者の数は増加していくことが予想されている。このように、がんは国民の健康や生活にとって重大な問題となっており「国民病」ともいえる疾患である。

そのような中、わが国のがん医療の充実を求める国民の声を受け、 平成18年に、がん対策を総合的かつ計画的に推進することを目的に 「がん対策基本法」が成立した。本法律の施行後、わが国のがん対策 の全体的な方向性と取り組みを初めて定めた「がん対策推進基本計 画」が、平成19年6月に策定され、わが国のがん対策は大きく動き始 めた。

このようながん対策の新たな転換期を迎え、がん患者の心のケアもまた、大きく進みつつある。本稿では、がん対策基本法成立後のわが国のがん対策について振り返り、その中でのがん患者の心のケアに関する取り組みについて解説する。

「がん対策基本法」の成立

わが国の政府によるがん対策の取り組みは、昭和59年度から開始