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Letters to the Editor

Serious outcomes associated with overdose of medicines containing barbiturates for treatment of insomnia

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THE SUICIDE RATE has remained high in Japan during the last two decades.[1] Restriction of access to means is an established suicide prevention strategy,[2] and limitation of prescribing barbiturates was followed by decreased death from those drugs in many countries.[3] However, in Japan, many psychiatrists still prescribe medicines containing barbiturates for treatment of insomnia. For example, a medical compound containing barbiturates was prescribed for 8–15% of patients with schizophrenia in Japan.[4]

We found that medicines containing barbiturates were overdosed by a substantial proportion of patients in Japan, and it was associated with serious outcomes. In a survey of all 190 patients (mean age 32.6 ± 0.95 years) who admitted to an emergency department in 1 year due to drug overdose between 2008 and 2009,[5] overdosed medicines were examined by interviewing patients and cohabitants and by urinary triage if conducted. Among 185 patients whose kinds of overdosed drugs were revealed, 29 patients (15.7%) overdosed medicines containing barbiturates. Overdose of such medicines tended to associate with older age (36.8 ± 2.41 years vs 31.6 ± 1.04 years, $P = 0.05$) and male sex (male 23.8%, female 13.3%, $P = 0.10$), while it was not associated with psychiatric diagnosis, simultaneous alcohol use, overdose of other antipsychotics, antidepressants, nor anxiolytics ($P = 0.79$, $P = 0.29$, $P = 0.14$, $P = 0.11$, and $P = 0.11$, respectively). Overdose of medicines containing barbiturates was associated with an increased death by drug intoxication ($n = 2$, 6.9%, vs $n = 0$, 0.0%, $P = 0.02$). Further, it was associated with increased odds of antibiotics treatment for pneumonia caused by drug intoxication after adjusting for age, sex, and simultaneous overdose of antidepressant and anxiolytics (odds ratio, 4.43; 95% confidence interval, 1.09–17.96; $P = 0.04$).

This report used the data on a public hospital that covered a wide area of Tokyo (970 000 inhabitants in the catchment area of 96 km^2), including many psychiatric clinics, thus may reflect a certain trend of prescription of Japanese psychiatrists. Although poisoning of drugs composes less than 5% of all suicide deaths,[1] Japanese psychiatrists should avoid prescription of medicines containing barbiturates for treatment of insomnia. Due to the small number of samples and lack of information, we could not adjust for demographic characteristics and physical comorbidity when examining fatal outcome. It would also be beneficial for other countries to investigate medicines that cause completed suicide due to drug overdose, and give a caution for easy prescription of those medicines.

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Aripiprazole in difficult-to-treat delusional disorder with co-morbid epilepsy

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OUR CURRENT UNDERSTANDING of the psychopharmacological treatment of persistent delusional disorder is limited by scanty scientific data that mostly consist of individual case reports and series only. A reasonable pharmacological treatment approach for patients with delusional disorder is a standard trial of an antipsychotic or, for somatic delusions, selective serotonin reuptake inhibitor.[1]

A 22-year-old man was brought to the Institute of Human Behaviour and Allied Sciences (a tertiary neuropsychiatric care centre) with a 2-year history of persistent persecutory belief. Examination revealed a well systematized delusion of reference and persecution with occasional transitory auditory hallucinations. Collateral history obtained included use of sodium valproate for episodes of generalized tonic clonic seizures (GTCS) for the last 3 years. There was no history of substance abuse and his family history was negative for any neuropsychiatric illness. The laboratory investigations and brain imaging, including electro-encephalogram, showed no abnormality and no cause could be ascertained for multiple episodes of GTCS. During the last 2 years, the patient was unsuccessfully treated with adequate dose and duration trials of three different atypi-

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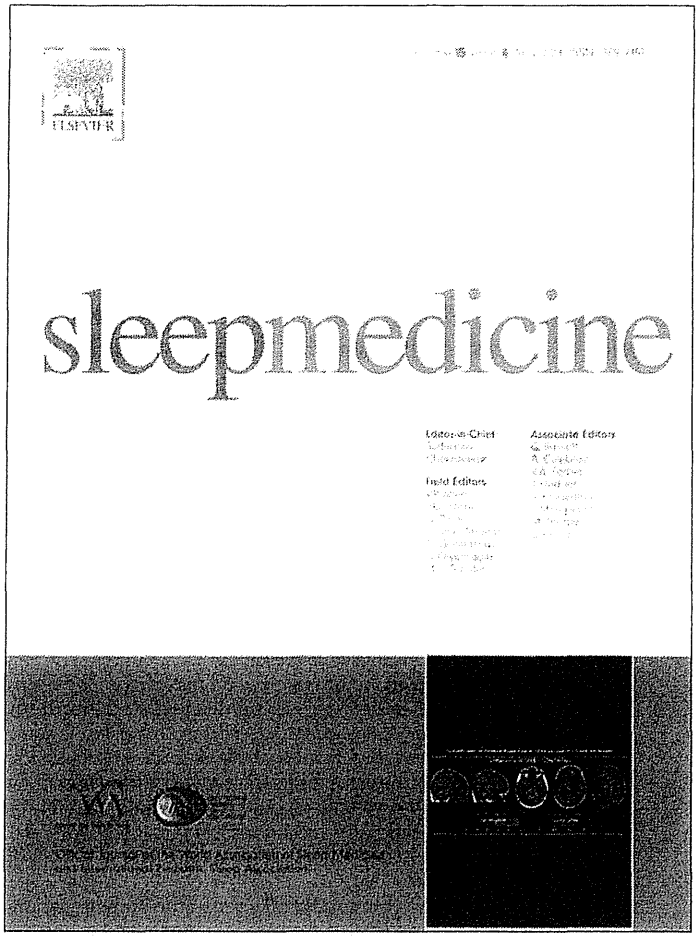

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Original Article

Suicide risk among individuals with sleep disturbances in Japan: a case–control psychological autopsy study

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ABSTRACT

Objective: This case–control psychological autopsy study aimed to explore a relationship between sleep disturbances and suicide among Japanese, as well as determine the importance and usability of screening for sleep disturbances in suicide prevention.
Methods: A semi-structured interview was conducted with the close family members of 49 adult suicide completers and 145 gender-, age-, and residential municipality-matched living controls. The survey included sections on demographics, sleep disturbances, and mental disorders. Conditional logistic regression analyses were performed to compare sleep disturbance prevalence between the two groups.
Results: A significantly higher prevalence of sleep disturbances was found among the suicide group (75.5%) compared to the controls (11.0%) (odds ratio [OR]=21.6, $p < 0.001$). The association remained significant after adjusting for mental disorders (OR = 12.7, $p < 0.001$). The population attributable risk percent of suicide associated with sleep disturbances and mental disorders was estimated to be 56.4% and 35.3%, respectively.
Conclusions: The study confirmed that sleep disturbances are an important risk factor of suicide, independent of mental disorders. Sleep disturbances accounted for a greater proportion of suicide cases than did mental disorders in the Japanese population given the higher prevalence, and could thus be considered an important target in suicide prevention in Japan.

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1. Introduction

Suicide is a major global health concern. The World Health Organization estimates that approximately one million people die by suicide every year. Japan's annual suicide rate is the highest of the seven major industrialized nations [1] and dramatically increased in 1998; since then, more than 30,000 individuals have died annually by suicide through 2011 [2]. Factors that increase risk of suicide and suicidal behaviors include mental disorders [3–4], physical disease [5–7], unemployment [8–11], adverse working conditions [10], divorce [11–12], childhood maltreatment [13–15], and family history of suicidal behavior [15].

Sleep disturbances may also represent a critical risk factor for suicide, and the early detection and treatment may greatly contribute to suicide prevention. A previous meta-analysis reported significant associations between sleep disturbances and suicidal thoughts and behaviors [16]. A Norwegian population-based study reported that age- and sex-adjusted hazard ratios for suicide among individuals with sleep disturbances ranged from 1.9 to 4.3, depending on the frequency [17]. Sleep disturbances that increased suicide risk included insomnia [18–23], nightmares [22,24–28], difficulty initiating sleep [29], and difficulty maintaining sleep [30]. Short sleep duration was also significantly associated with suicide risk [28,31–33]. The association was not explained by mental disorders; rather, it was independent of mental disorders [16,17,29,31,34]. Although previous studies have consistently shown an association between sleep disturbances and suicide, the usefulness of sleep disturbance assessment as a marker of suicide, compared to mental disorders, has not been clearly

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evaluated, and no quantitative measures, such as population attributable risk proportion (PARP) and estimated post-screening probability of suicide, have been provided.

In addition, the relationships between sleep disturbances, mental disorders, and suicide may differ by culture and country. Limited data are available regarding the relationship between sleep disturbances and suicide in Japan. Only a prospective cohort study of 13,259 middle-aged adults indicated that difficulty maintaining sleep increased risk of suicide [30]. As for suicidal tendencies, there were significant associations between feelings of insufficient sleep and suicide ideation among middle-aged female [35] and male workers [36]. Insomnia and overall sleep disorders were also significantly associated with increased risk of suicide ideation among psychosomatic clinic outpatients [37]. These findings suggest that sleep disturbances are also a risk factor for suicide in Japan. However, sleep time in Japan is the second shortest in the world after Korea [38], and the prevalence of mental disorders tends to be lower in Asian countries, including Japan, compared to Western countries [39]. These country-dependent differences may influence the impact that sleep disturbances or mental disorders have on suicide prevention.

In the present study, we analyzed data from the first Japanese case–control psychological autopsy study [40] to assess the association between sleep disturbances and suicide in Japan, after adjusting for mental disorders including depression. To verify a comparable impact of sleep disturbances in suicide prevention, we also calculated a PARP of suicide associated with sleep disturbances, as well as mental disorders, and also simulated posterior probabilities of suicide among screening positives for populations with different risks of suicide when sleep disturbance assessment was used in a screening of suicide.

2. Methods

2.1. Study participants

The study included 52 individuals over 20 years of age who died by suicide in various areas of Japan. Bereaved family members who visited prefectural Mental Health Welfare Centers for individual support or survivor meetings were asked to participate at the time of visit. Suicide case respondents represented various areas of Japan. The surveys, described below, took place from January 2007 to July 2009. The mean period from incidence of suicide to administration of the survey was 17.4 months (SD, ±14.7 months).

Control participants recruited from September through November 2009 were living individuals matched to the suicide cases by gender, age (5-year age group), and residential municipality. Up to 30 control candidates for each suicide case were randomly selected from the Basic Resident Register. Interviewers employed by a research company contacted the candidates by first sending an invitation letter and then visiting their homes if there was no response to the letter. Once a candidate agreed to participate, the interviewer contacted the closest family member living with the candidate. A total of 152 controls and their family members agreed to participate in the study; however, the genders of three suicide cases were found to be wrongly coded after data collection. Those cases and the seven controls matched to them were subsequently excluded from analyses, giving a final dataset of 49 suicide cases and 145 matched controls.

2.2. Procedures

Information on the suicide cases and controls was collected through an interview with a family member for each. An informant for a suicide case was a family member who had a close relationship and lived together with the deceased. An informant for a control was the closest family member living together with him/her. If two or more close family members were available, the highest selection priority was given to spouse, followed by parent and child. Data collection through interview surveys started once informants and controls gave consent in writing to participate in the study.

A semi-structured interview was conducted using an assessment instrument for psychological autopsy studies described below. Interviews for suicide cases were conducted by paired local investigators consisting of a psychiatrist and another mental health professional such as a public health nurse. All local investigators participated in a three-day training program for the study. Interviewers from the research company received a day-long training session to be qualified to recruit controls as described above and also conduct their interviews. Data coding and entry were performed by the research company staff.

The study protocol was approved by the Research Ethics Committee of the Faculty of Medicine/Graduate School of Medicine at the University of Tokyo and the Ethics Committee of the National Center of Neurology and Psychiatry.

2.3. Assessment instruments

The assessment instrument was based on one formulated by the Beijing Suicide Research and Prevention Center in China [41] and modified through a preliminary study with 25 suicide cases to accommodate situations and interests in Japan. The instrument consisted of eight sections: (1) socio-demographic background, (2) previous suicidal behaviors (and characteristics of completed suicides for suicide cases), (3) childhood and school experiences, (4) job characteristics (for those employed), (5) financial problems, (6) quality of life, (7) physical conditions (including sleep disturbances), and (8) mental disorders. This study mainly used socio-demographic background, sleep disturbances, and mental disorders for data analyses.

Socio-demographic variables included gender, age (or age of death for suicide cases), education, marital status, employment status, and household income in the past year. Education was categorized as junior high school graduate (11 years of education or less), high school graduate (12–15 years), and college graduate or higher (16+ years). Marital status was dichotomized into 'married' and 'not married', and employment status into 'employed' and 'not employed'.

Overall sleep condition in the month prior to suicide or the survey was dichotomized into 'disturbed' or 'not disturbed'. When a family member was unable to recall the deceased's sleep disturbances, we coded this response as 'unknown' and interpreted this as 'not disturbed' in the data analysis. Sleep disturbances were divided into six categories: 'difficulty falling asleep', 'interrupted sleep', 'early morning awakening', 'lack of deep sleep', 'day-night reversal', and 'other'. Categories for frequency of sleep disorders included 'none', '1–2 days', '3–4 days', '5–6 days', 'every day', and 'unknown' ('3–4 days' and '5–6 days' were combined for data analyses due to few frequencies). Continuity of sleep disorders was dichotomized into 'more than one year (prior to suicide)' or 'less than one year'.

A psychiatric structured interview schedule was used with suicide cases at the time of death and controls at the time of the interview to assess mental disorders such as alcohol-related disorders (alcohol dependence and alcohol abuse), drug-related disorders (drug dependence and drug abuse), mood disorders (major depressive disorder, dysthymic disorder, and bipolar I and II disorders), psychotic disorders (schizophrenia, brief psychotic disorder, and other psychotic disorder), and anxiety disorders (panic disorder, generalized anxiety disorder, and acute and post-traumatic stress

disorders). The interview schedule was based on an assessment guide used in a psychological autopsy study in China [41], the Structured Clinical Interview for DSM-IV (SCID) [42], and other relevant tools. A preliminary adaptation was developed by translating the original to Japanese and then modifying questions from the SCID Axis I disorders. The instrument was further modified through a series of pilot studies, using interviewer experiences and feedback from family members of suicide cases.

2.4. Data analysis

Sleep disturbance prevalence was compared between suicide cases and controls. The statistical significance of differences in frequencies was tested using conditional logistic regression, since the number of controls matched to one suicide case ranged from one to six. The odds ratio (95% confidential interval [CI]) was calculated for suicide associated with variables relevant to sleep disorders such as type, frequency, and continuity of disturbances. Relationships were also analyzed between sleep disturbances and suicide, adjusted for depressive disorders or mental disorders. To identify which disorders have a higher priority in suicide risk assessment of the general population, population attributable risk percent (PARP) [43] of suicide was estimated among those affected by sleep disturbances or mental disorders. Posterior probabilities of suicide occurring under sleep disturbances were calculated to identify for which of three different target populations sleep disturbance screening was most useful as a marker of suicide. Data analyses were performed using IBM SPSS Statistics ver.19 (IBM, Armonk, NY, USA). $P < 0.05$ (two-tailed) was considered statistically significant.

3. Results

3.1. Demographics and suicide-related characteristics

Table 1 presents demographics for the suicide and control groups. The proportion of junior high school graduates (11 years of education or less) was higher for the suicide cases than the controls. The suicide group also included more individuals who had not been married and had a lower employment rate than the control group.

3.2. Association between sleep disturbances and suicide

Sleep disturbances, experienced by 75.5% of suicide cases and 11.0% of controls, were significantly associated with suicide (OR = 21.6, 95% CI = 7.6–61.5, $p < 0.001$) (Table 2). Of the five types of sleep disturbances, 'difficulty falling asleep' produced the highest odds ratio (OR = 51.7, 95% CI = 6.9–390.1, $p < 0.001$). Half of the suicide cases experienced daily sleep disturbances, which had the highest odds ratio among other frequency categories (OR = 47.1, 95% CI = 9.5–232.8, $p < 0.001$). Individuals who experienced sleep disturbances for one year or longer were 11.8 times more likely to die by suicide (CI = 3.9–35.6, $p < 0.001$).

Significant relationships between sleep disturbances and suicide were observed when adjusted for depressive (OR = 9.7, 95% CI = 3.2–29.5, $p < 0.001$) or any mental disorders (OR = 12.7, 95% CI = 4.0–40.3, $p < 0.001$). Depressive disorders and mental disorders alone were both significantly associated with suicide (OR = 68.7, 95% CI = 9.2–510.8, $p < 0.001$ and OR = 21.1, 95% CI = 7.4–60.2, $p < 0.001$, respectively).

A PARP of suicide associated with sleep disturbances was estimated to be 56.4%, based on the multivariate odds ratio associated with sleep disturbance controlling effects for any mental disorders (OR = 12.7) and the prevalence of sleep disturbances in the control group (11%). On the other hand, a PARP of suicide associated with any mental disorders was 35.3%, based on the multivariate odds ratio associated with any mental disorders controlling effects for sleep disturbances (OR = 12.3) and the prevalence of sleep disturbance in the control group (4.8%).

3.3. Usefulness of sleep disturbance assessment as a marker of suicide

The usefulness of sleep disturbance assessment as a marker of suicide was examined using posterior probabilities among screening positives (i.e., cases with sleep disturbances) as an indicator, under simulated scenarios of three difference target populations, i.e., people at the greatest risk of suicide (e.g., severely depressed patients), people at high risk of suicide (e.g., divorced or unemployed patients), and the general population in Japan (Table 3). The detailed calculation procedure is presented in Appendix. Posterior probabilities of suicide cases among screening positives were estimated to be 43.3% and 6.5% per year for people at the greatest

Table 1
Demographic characteristics of suicide cases and controls: the nation-wide case–control psychological autopsy study in Japan, 2007–2009.

	Suicide cases ($N = 49$) n (%)	Controls ($N = 145$) n (%)	p	Odds ratio (95% CI)
Gender				
Male	41 (83.7)	120 (82.8)	REF	1.00
Female	8 (16.3)	25 (17.2)	0.899	0.85 (0.45–2.03)
Age (years)				
20–34	13 (26.5)	35 (24.1)	REF	1.00
35–44	14 (28.6)	40 (27.6)	0.910	0.96 (0.45–2.04)
45–64	14 (28.6)	49 (33.8)	0.608	0.82 (0.39–1.75)
65-	8 (16.3)	21 (14.5)	0.967	1.02 (0.42–2.46)
Education (years)				
11or less	14 (28.6)	24 (16.6)	0.047	2.93 (1.02–8.46)
12–15	22 (44.9)	72 (49.7)	0.575	1.27 (0.55–2.94)
16-	13 (26.5)	48 (33.1)	REF	1.00
Marital status				
Married	31 (63.3)	117 (80.7)	REF	1.00
Not married	18 (36.7)	28 (19.3)	0.003	5.14 (1.75–15.09)
Employment status				
Employed	34 (69.4)	119 (82.1)	0.009	0.20 (0.06–0.67)
Not employed	15 (30.6)	26 (17.9)	REF	1.00

Conditional logistic regression analysis; CI: confidence interval; REF: reference group.

Table 2
Sleep disturbance prevalence among suicide cases and controls, and estimated associations (odds ratios) with suicide: the nation-wide case–control psychological autopsy study in Japan, 2007–2009.

Sleep disturbances	Suicide cases ($N = 49$)	Controls ($N = 145$)	Crude		Multivariate*		Multivariate**	
	n (%)	n (%)	Odds ratio (95%CI)	p	Odds ratio (95%CI)	p	Odds ratio (95%CI)	p
Experienced disturbance	37 (75.5)	16 (11.0)	21.6 (7.6–61.5)	<0.001	9.7 (3.2–29.5)	<0.001	12.7 (4.0–40.3)	<0.001
Types								
Difficulty falling asleep	18 (36.7)	2 (1.4)	51.7 (6.9–390.1)	<0.001	16.3 (2.0–136.3)	0.010	31.6 (2.9–342.5)	0.005
Interrupted sleep	15 (30.6)	3 (2.1)	14.7 (4.2–51.3)	<0.001	7.6 (1.7–34.8)	0.009	11.4 (2.3–57.0)	0.003
Early-morning awakening	14 (28.6)	4 (2.8)	10.7 (3.5–33.0)	<0.001	3.5 (0.8–14.6)	0.093	6.0 (1.4–26.5)	0.017
Lack of deep sleep	20 (40.8)	5 (3.4)	19.5 (5.7–66.5)	<0.001	9.9 (2.3–42.8)	0.002	14.0 (3.1–63.2)	0.001
Day-night reversal	3 (6.1)	2 (1.4)	4.4 (0.7–27.6)	0.113	5.1 (0.5–51.6)	0.168	7.4 (0.6–82.4)	0.102
Others	9 (18.4)	5 (3.4)	5.0 (1.5–16.7)	0.009	14.0 (1.2–160.9)	0.034	7.5 (1.3–44.2)	0.026
Frequency (per week)								
None	12 (24.5)	129 (89.0)	1.00	REF	1.00	REF	1.00	REF
1–2 days	2 (4.1)	5 (3.4)	2.6 (0.4–16.5)	0.31	1.6 (0.2–13.4)	0.66	1.6 (0.2–13.7)	0.66
3–6 days	4 (8.2)	2 (1.4)	20.9 (2.3–187.3)	0.007	7.7 (0.5–130.2)	0.16	6.0 (0.2–235.0)	0.34
Everyday	25 (51.0)	7 (4.8)	47.1 (9.5–232.8)	<0.001	15.2 (2.9–79.0)	0.001	20.2 (3.8–105.9)	<0.001
Unknown	6 (12.2)	2 (1.4)	-		-		-	
Continuity								
1 year or longer+	17 (34.7)	9 (6.2)	11.8 (3.9–35.6)	<0.001	3.0 (0.8–11.5)	0.114	4.0 (1.1–14.58)	0.041

Conditional logistic regression analysis; CI: confidence interval; REF: a reference group.
* Adjusted for depressive disorders.
** Adjusted for any mental disorders.
\- "Unknown" cases were not included in analyses.
\+ Prior to suicide for suicide cases and prior to interview survey for controls.

Table 3
Usefulness of sleep disturbance assessment as the marker of suicide: prior and posterior probabilities of suicide in simulated cases of screening programs in three different target populations.

Target population	Prior probability of suicide before the screening (% per year)	Posterior probability of suicide when sleep disturbances are present (% per year)	Posterior probability of suicide when sleep disturbances are absent (% per year)
People at the greatest risk of suicide (e.g., severely depressed patients)	10	43.3	3.0
People at high risk of suicide (e.g., divorced, unemployed)	1	6.5	0.3
General population*	0.025	0.2	0.01

* Based on an average annual suicide rate in Japan, 1998–2012.

risk and high risk of suicide, respectively, while it was only 0.2% for the general population.

4. Discussion

The analysis of data from the Japanese case–control psychological autopsy study confirmed that there is a significant association between sleep disturbances and suicide in the Japanese population. Suicide risk in people with sleep disturbances was estimated to be 21.6 times higher compared to those without sleep disturbances, and remained high even after adjustment for depressive or any mental disorders (9.7 times higher when adjusted for depressive disorders; 12.7 times higher for any mental disorders). The observed odds ratio of this study was higher than those reported in previous psychological autopsy studies showing that adolescent suicide completers had a sleep difficulty rate 7.0 times higher, when adjusted for affective disorders, compared to living controls [34], and that suicide risk was 2.4 times higher in depressed community residents with sleep disturbances than in depressed controls [21]. In the present study, the odds ratios for suicide associated with sleep disturbances adjusted for major depression or any mental disorder had large 95% CIs. Thus, caution is required in drawing any conclusions based on these odds ratios.

The PARP estimated in this study indicated that 56.4% of suicides could be explained by sleep disturbances and 35.3% by mental disorders. This is likely due to the fact that the relative risks of suicide among people with sleep disturbances and those with any mental disorder was very similar (21.6 versus 21.1), while the prevalence of sleep disturbances in the general population (controls) was higher (11.0%) compared to those with mental disorders (4.8%). These findings suggest that treatment of sleep disturbances, which had almost the same relative risk as mental disorders and a higher PARP, is more beneficial to suicide prevention and necessitates more strategies that effectively target the prevention or treatment of sleep disturbances.

We examined the usefulness of sleep disturbance assessment as a marker of suicide in three simulated scenarios with different prior probabilities of suicide. An estimated posterior probability of suicide was 43.3% per year among screening positives who had sleep disturbances, when the screening was applied to people at 10% risk of suicide per year or equivalent, such as severely depressed patients. On the other hand, the estimated posterior probability was 6.5% per year when the screening of suicide based on sleep disturbances was applied to people at 1% risk of suicide per year, such as those recently divorced or those with long-term unemployment. Thus, assessing sleep disturbances as a suicide risk index would be effective in both clinical scenarios, and may help identify a target population for intensive continuous care, especially among people already at high risk. Moreover, sleep disturbance assessment can be used as a suicide marker for vulnerable individuals who are in medical/psychological/social services. However, given that the estimated posterior probability of suicide was only 0.2% per year in the general population, suicide risk assessment based on sleep disturbances may not be effective in general screening. Yet, this does not eliminate the possibility that screening of depressive disorders based on sleep disturbances

can be used effectively [44], since the prevalence of depressive disorders is much greater than suicide mortality.

5. Limitations

There were several limitations to the present study. First, the sample size was relatively small, and differences among subgroups such as gender and age could not be explored. Second, the non-randomized sampling of suicide cases was possibly biased. Cases were selected using relatives who sought help from prefectural Mental Health and Welfare Centers or participated in survivor support programs. Suicide completers who had lived alone were thus not included. In addition, the response rate for controls was relatively low (20%). Third, information bias could be a critical issue; informants of the suicide group may have exaggerated the degree or causal relation of sleep disturbances in deceased individuals, and interviewers may have been inclined to record information they associated with suicide. At the same time, only sleep disturbances clearly recalled by family members were included in the data analysis. More sleep disturbances might have occurred among the deceased individuals. It should be also noted that the quality of the assessment of some of these sleep problem items may be limited. For instance, a family member would be unaware of a respondent's lack of deep sleep if his/her self-report or a family member's observation of his/her behaviors during sleep was not available. Fourth, some cases had a period of a few years from incidence of suicide to administration of the survey; informants in these cases may have forgotten that sleep disturbances had occurred in deceased individuals over time. Moreover, we did not use a standardized tool to evaluate the sleep disturbances of suicide cases and controls, so the information obtained through informants may not have been accurate. Finally, given that prevalence rates of psychopathology and average sleep durations differ by country (i.e., shorter sleep time in Japan [38] and lower prevalence of mental disorders in Asian countries [39]), generalization of the study results requires caution.

Future studies need to explore associations between sleep disturbances and suicide among different sub-groups (e.g., sex, age), use a standardized measurement for sleep disturbances, and add other variables to identify additional sleep-related factors associated with suicide (e.g., wake time, nightmares). We would also recommend that future studies explore cultural differences in the association between sleep disturbances and suicide, and to examine the effectiveness of treatment for sleep disturbances to reduce suicide relevant risks (e.g., suicidal ideation).

In conclusion, sleep disturbances were significantly associated with suicide, even after adjustment for depressive or any mental disorders. Our findings indicate that identifying sleep disturbances would be more efficient in suicide prevention than focusing on mental illnesses, and screening for sleep disturbances has high usability potential in preventing suicide among high-risk individuals in Japan.

Conflict of interest

The ICMJE Uniform Disclosure Form for Potential Conflicts of Interest associated with this article can be viewed by clicking on the following link: http://dx.doi.org/10.1016/j.sleep.2013.11.789.

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Appendix I

The following is the list of questions regarding sleep disturbances.

- Had she/he had any sleep disturbances during the last month? –Yes/No/Unknown.
  (If 'yes,' please proceed to the following questions.)
- What kind of sleep disturbances had she/he suffered from? (multiple answers allowed)
  - Difficulty falling asleep at night; taking many hours to fall asleep
  - Sleep interrupted very often during the night
  - Waking up too early in the morning
  - Unrestful sleep (lack of deep sleep)
  - Day-night reversal
  - Other
- On average, how many days per week had she/he had such sleep disturbances during the last month? – None/1–2 days/ 3–4 days/5–6 days/Every day/Unknown
- Had she/he been suffering from such sleep disturbances for more than a year prior to death?—Yes/No/Unknown

Appendix II

We calculated posterior probabilities of suicide among screening positives with sleep disturbances by suicide risk (i.e., people at the greatest risk of suicide, people at high risk of suicide, and general population having 10% (0.1), 1% (0.01), and 0.025% (0.00025) risk per year) as follows:

$$\text{Prior odds} = \frac{\text{Prior probability}}{1 - \text{Prior probability}}$$

$$\text{Likelihood ratio(LR)} = \frac{\text{Sensitivity}}{1 - \text{Specificity}}$$

$$\text{Sensitivity} = \text{Proportion of sleep disturbances in the suicide case group} = \frac{\text{the number of suicide cases with sleep disturbances}}{\text{the number of suicide cases in total}}$$

$$\text{1-Specificity} = \text{Proportion of sleep disturbances in the control group} = \frac{\text{the number of controls with sleep disturbances}}{\text{the number of controls in total}}.$$

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VOLUME 33 · NUMBER 2 · JANUARY 10 2015

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CORRESPONDENCE

Reply to B. Gyawali et al

We thank Gyawali et al[1] for their questions and concerns regarding our recent report of a randomized controlled trial (RCT) on communication skills training (CST).[2] Their first comment is that the percentage of oncologists who wanted to participate in our study is lower (19.6%) than expected; they suggest as reasons for this that Japanese oncologists suffer fewer patient complaints and feel confident in communicating with their patients. As we reviewed previous RCTs on communication skills training, we found participant rates of 15% (81 of 550) for oncologists in the report by Razavi et al[3] and Delvaux et al,[4] and 18% for nurses and 55% for physician trainees in the article by Curtis et al.[5] However, in our study, 11 of 15 (73%) oncologists assigned to the control group participated in the CST workshop after the study. More than 80% of oncologists in Japan reported some perceived burden when communicating bad news to patients.[6] Therefore, we disagree with the claim by Gyawali et al[1] that the participant rate is low, owing to that Japanese oncologists feel less difficulty with bad news communication. On the other hand, we agree with their claim that many Japanese oncologists may have no time to study communication skills because they are always busy and do not know what benefit CST will provide. Therefore, we believe that our study published in *Journal of Clinical Oncology* will contribute to the promotion of oncologists' understanding of CST.

Second, Gyawali et al[1] express concern that the oncologists in the intervention group might have had more patients who were receiving good news. In this study, 8.4% of the intervention group consultations were for the communication of bad news, 29.1% were for the delivery of good news, and 62.5% were for sharing neutral news; in contrast, 6.0% of control group consultations were for the communication of bad news, 23.6% for good news, and 70.4% for neutral news. The results showed no significant differences ($\chi^2 = 7.74$; $P = .09$).[2] Another concern was expressed by Gyawali et al with respect to the contents of the CST workshop; specifically, that the workshop might have addressed only bad news and not good news consultations. Although our developed CST workshop program covered three bad news scenarios (diagnosis of advanced cancer, recurrence, and stopping anticancer treatment), which were based on the results of our previous survey for oncologists regarding difficult communication situations,[7] the program included not only specific communication skills (based on the results of our previous surveys of patients' preferences),[8,9] but also many fundamental skills. It is difficult to assess the effect of the CST program on real-life clinical consultations, because many of the desired behaviors are context dependent. For example, an oncologist will have more opportunity to make an empathic response or respond to cues if the patient expresses his/her emotion or psychosocial concerns. However, in this study, no attempt was made to select certain types of consultations or patients. It was impossible to ensure that the context (good/bad news) or reason for consulting (new diagnosis/routine follow-up) was constant for an individual oncologist at each time point. Despite these limitations, the patient outcomes could be assessed well in the real-world practice.

Third, we agree with the claim by Gyawali et al[1] that patients with advanced or newly diagnosed disease might be more prone to anxiety and depression. In this study, the number of patients with recurrence or metastasis in the two groups was not significantly different ($\chi^2 = 2.89$; $P = .236$).[2] Although the percentage of patients currently receiving treatment was different among the two groups (40.4% in the intervention *v* 27.5% in the control group),[2] we do not think this skewed the results. The levels of psychological distress, satisfaction with the oncologist, and trust in the oncologist expressed by patients currently receiving treatment were significantly worse compared with levels expressed by patients not currently undergoing treatment (respectively, $t = -1.97$ and $P = .049$; $t = 3.83$ and $P = .001$; $t = 3.29$ and $P < .001$). We used real-world clinical settings with consecutive and consenting patients because that is likely the realistic approach for identifying effects of a CST program on patient outcomes.

Fourth, we calculated and showed 13 participants in each group as a sample size to detect a significant between-group difference in our study on the basis of the results of difference in empathic behavior in our previous open-label trial.[10] Furthermore, we showed the desired sample size, including missing values, in our study protocol.

Because communication is interaction between persons, and personal reaction and experience are subjective, it is difficult to perform an objective and scientific assessment of communication. Despite these many limitations, many additional efforts in this research area are expected because communication between patients and oncologists is an important issue.

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Disclosures provided by the authors are available with this article at www.jco.org.

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Reply to B. Gyawali et al

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No relationship to disclose

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JOURNAL OF CLINICAL ONCOLOGY ORIGINAL REPORT

Effect of Communication Skills Training Program for Oncologists Based on Patient Preferences for Communication When Receiving Bad News: A Randomized Controlled Trial

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ABSTRACT

Purpose
The aim of this study was to identify the effects of a communication skills training (CST) program for oncologists, developed based on patient preferences regarding oncologists' communication.

Participants and Methods
Thirty oncologists were randomly assigned to either an intervention group (IG; 2-day CST workshop) or control group (CG). Participants were assessed on their communication performance during simulated consultation and their confidence in communicating with patients at baseline and follow-up. A total of 1,192 patients (response rate, 84.6%) who had consultations with the participating oncologists at baseline and/or follow-up were assessed regarding their distress using the Hospital Anxiety and Depression Scale, satisfaction with the consultation, and trust in their oncologist after the consultation.

Results
At the follow-up survey, the performance scores of the IG had improved significantly, in terms of their emotional support ($P = .011$), setting up a supportive environment ($P = .002$), and ability to deliver information ($P = .001$), compared with those of the CG. Oncologists in the IG were rated higher at follow-up than those in the CG in terms of their confidence in themselves ($P = .001$). Patients who met with oncologists after they had undergone the CST were significantly less depressed than those who met with oncologists in the CG ($P = .027$). However, the CST program did not affect patient satisfaction with oncologists' style of communication.

Conclusion
A CST program based on patient preferences is effective for both oncologists and patients with cancer. Oncologists should consider CST as an approach to enhancing their communication skills.

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INTRODUCTION

A number of studies examining patient-physician communication in cancer consultations have revealed numerous difficulties, because patients with cancer suffer from intense emotional anguish, particularly when they receive bad news about their disease. The ability of physicians to empathize—defined in medical settings as a "cognitive attribute and behavior that involves an understanding of experiences, concerns and perspectives of the patient"[1(p1183)]—has been effective in helping patients adjust to a life-threatening disease[2,3] and correlated with a low level of psychological distress.[4] Therefore, communication between patients and physicians has been viewed as a core clinical skill that merits a considerable investment of time and resources in training.

Communication skills training (CST) is reported to be effective in improving physicians' communication skills, such as using open questions and showing empathy toward patients; it is recommended for medical staff. However, there is no evidence to support a beneficial effect of CST on patients' mental health or patient satisfaction.[5] One possible reason for this is that findings have been based only on experts' and oncologists' opinions and have not necessarily reflected those of patients.[6-9] Oncologists' communication behaviors preferred by patients were linked in a previous study to lower psychological distress and higher satisfaction in patients.[10] Therefore, interventions to enhance oncologists' communication skills that take into account patients' preferences for receiving information are needed.[7,10]

Our previous quantitative and qualitative surveys revealed that patient preferences regarding the

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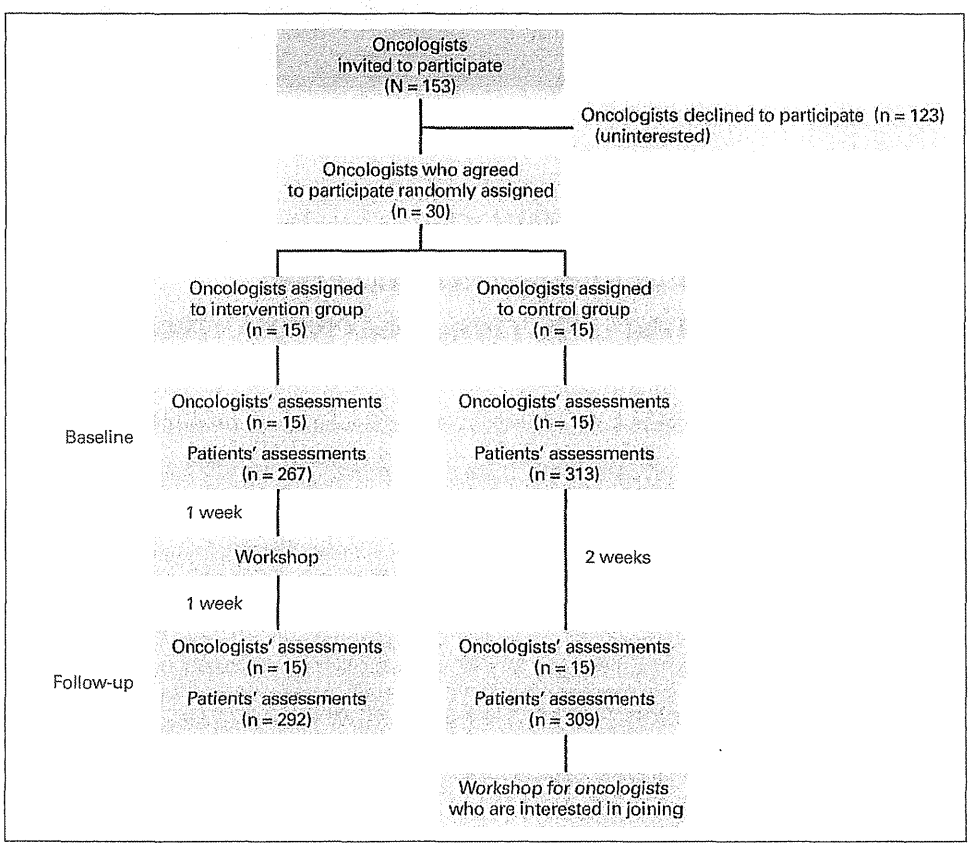

Fig 1. Study flow diagram.

communication of bad news consist of four factors: setting, how the news is delivered, provision of various types of information, and emotional support.[11] Emotional support has also been found to be the most important factor for patients.[12] On the basis of these findings, we previously developed a 2-day CST program. This program was intended to improve the empathic communication and effective behaviors of oncologists and their confidence in their ability to communicate with patients.[13]

Building on this work, the aim of this study was to identify the effects of this CST program for oncologists, using patient preferences, by evaluating oncologists' behaviors during simulated consultation, their confidence in communicating with patients, and patients' distress and satisfaction with the consultation.

PARTICIPANTS AND METHODS

Participants

Oncologists. Staff of the National Cancer Center (NCC) Hospital, Tokyo, and Hospital East, Chiba, Japan, were recruited.

Patients. Outpatients who were attending follow-up medical appointments with oncologists at the NCC hospitals were recruited after consultation. The eligibility criteria were as follows: patients who had received a diagnosis of cancer, were age ≥ 20 years, were judged capable of completing the survey physically and cognitively, and were capable of understanding spoken and written Japanese.

All participants were given information about this study and provided written informed consent. The institutional review board and ethics committee of the NCC approved this study.

Procedures

After providing informed consent, oncologists were randomly assigned to an intervention group (IG; 2-day CST workshop) or control group (CG). The study flow diagram is shown in Figure 1.

The baseline survey required oncologists to participate in a simulated consultation, in which they relayed a diagnosis of incurable advanced cancer to a simulated patient (SP), and to complete a questionnaire requesting information about their demographic characteristics (age, sex, and marital status), medical experience (specialty, clinical experience, and clinical experience in oncology), and perceived confidence in communicating with a patient. On days when a participating oncologist had consultations in the outpatient clinic, all eligible outpatients were invited to participate in the study after their follow-up medical visit. Patients who provided written informed consent were asked to complete and return within 1 week a series of questionnaires evaluating their psychological distress (Hospital Anxiety and Depression Scale [HADS]), their satisfaction with their oncologist's communication during the consultation, their trust in the oncologist, and their demographic characteristics. If the questionnaires contained any blanks, a single attempt was made to obtain the missing information by telephone or mail.

After the CST workshop in the IG or 2 weeks after baseline in the CG, the same variables collected at baseline were collected as follow-up data. After the follow-up survey, the oncologists assigned to the CG were allowed to participate in the workshop if they desired.

Workshop

Table 1 lists components of the CST program based on the SHARE model. In accordance with our previous surveys of the preferences of Japanese patients with cancer regarding the disclosure of bad news,[11,12,14,15] the CST program adopted the conceptual communication skills model consisting of four dimensions, referred to as SHARE: S, setting up a supportive environment for the interview; H, considering how to deliver the bad news; A,

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Table 1. Components of CST Program Based on SHARE Model

Component	Description
Conceptual communication skills model: SHARE	
S	Setting up supportive environment for interview (eg, greeting patient cordially, looking at patient's eyes and face)
H	Considering how to deliver bad news (eg, not beginning bad news without preamble, checking to see whether talk is fast paced)
A	Discussing additional information that patient would like to know (eg, answering patient's questions fully, explaining second opinion)
RE	Providing reassurance and addressing patient's emotions with empathic responses (eg, remaining silent out of concern for patient's feelings, accepting patient's expression of emotions)
Module	
Lecture	Introduction, communication skills model, evidence of preferences of patients with cancer regarding communication
Video trigger	Delivering bad news using communication skills
Role playing	Delivering bad news using communication skills with scenarios
Peer discussion	Solving problems occurring in role playing, final summary
Scenarios for breaking bad news	Diagnosis of advanced cancer
	Recurrence
	Stopping anticancer treatment
Small-group setting	Four participants
	Two facilitators
	One simulated patient
Schedule	
Day 1	Orientation (10 minutes)
	Icebreaking (20 minutes)
	Lecture (30 minutes)
	Video trigger (30 minutes)
	Role playing with peer discussion (60 minutes × 4)
Day 2	Role playing with peer discussion (60 minutes × 4)
	Summary (30 minutes)

Abbreviation: CST, communication skills training.

discussing various additional information that patients would like to know; and RE, providing reassurance and addressing patients' emotions with empathic responses. The program particularly emphasized the RE component, because it has been shown to be the most important for patients[11,15] and also to be one of the most difficult communication skills for oncologists.[15] The face validity of the conceptual model in the CST program and the feasibility of the CST program were confirmed by two psychiatrists, one psychologist, and two oncologists who were experienced attending staff in clinical oncology, with knowledge about communication between patients and oncologists; this was achieved using the Delphi method[16] after reviewing previous studies and by holding preliminary workshops before this study.

The program was a participant-centered approach and consisted of an icebreaking discussion, a 1-hour computer-aided didactic lecture with text and video, 8 hours of role playing with SPs, and discussions on this role playing. It lasted a total of 2 days and was based on previous studies.[5,17,18] The lecture provided during this program cited evidence of the most important and common patient preferences regarding the communication of bad news, such as empathic responses and encouragement to ask questions, as well as variability of patients' preferences, such as discussion of prognosis and being dispassionate, and showed how to check and elicit patient preferences. After this lecture, the oncologists were divided into groups of four, with two facilitators each, for role playing and discussion. During the role playing and discussion, the participants were required to consider a patient's emotions and concerns caused by bad news, cognition of his or her disease, social situation, and information that he or she would want to know, by empathizing with the patient. Facilitators led the role playing and discussion on the potential communication-related preferences and emotions of the patient. The facilitators were psychiatrists, psychologists, and oncologists, all of whom had ≥ 3 years of clinical experience in oncology and had participated in specialized 30-hour training workshops for facilitating communication skills in oncology. The SPs, individuals who had ≥ 3 years of experience in medical school, also participated in the 30-hour training workshops. For the role playing, many scenarios were drawn up tailored to each oncologist's specialty, presenting three different situations that required the sharing of bad news with a patient: diagnosis of advanced cancer, recurrence of cancer, and cessation of anticancer treatment. In a previous study, these situations were found to be difficult to deal with in practice by oncologists.[18]

Oncologists' Outcome Measure

Objective performance of communication skills. We videotaped the oncologists' performance during simulated consultations at baseline and follow-up. Each simulation involved a total of four SPs, who had ≥ 3 years of experience in medical school and had been trained in simulating the standard reactions of patients for ≥ 60 hours via a manual. On the basis of previous study methods,[13,19] the frequencies of each type of performance and utterance during their consultations were assessed using the 27 SHARE categories for analyzing the impressions of oncologists' performance (Table 2). Each video was coded in terms of SHARE category in a random order by two blinded coders, who had been trained for 30 hours for this task independently on two occasions with a rating manual. The averages of the intracoder correlation coefficients for each group of categories were 0.79 (range, 0.72 to 0.92) and 0.76 (range, 0.70 to 0.94), and the average of the intercoder correlation coefficient was 0.78 (range, 0.58 to 1.00).

Confidence in communication with patients. Confidence in communicating with patients was assessed using two questionnaires consisting of 32 items related to SHARE[11,13,19] and 21 items established by Baile et al.[13,17,20] All items were rated on a 10-point Likert scale, ranging from "not at all" to "extremely." The total scores (SHARE: range, 32 to 320; confidence questionnaire: range, 21 to 210) were used to rate oncologists' confidence in communicating with patients.

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Table 2. Comparison of Mean Total Performance Score for Physicians During Consultation Over Time and Between Groups

Communication Skill	Baseline				Follow-Up				F	P	Bonferroni Correction*
	IG		CG		IG		CG				
	Mean	SD	Mean	SD	Mean	SD	Mean	SD			
Setting up supportive environment for interview	8.73	1.83	7.87	2.00	10.93	2.09	8.13	1.92	11.98	.002	X
Greeting patient cordially	1.00	1.73	0.53	1.41	3.20	1.66	0.67	1.45	18.14	< .001	X
Looking at patient's eyes and face	3.73	0.59	3.73	0.59	3.87	0.52	3.73	0.46	2.06	.163	
Taking sufficient time	4.00	0.00	3.60	1.06	3.87	0.35	3.73	0.80	0.08	.775	
Considering how to deliver bad news	18.53	5.24	15.73	7.40	25.93	8.57	14.67	7.01	13.18	.001	X
Encouraging patient to ask questions	3.33	1.11	2.20	1.82	3.27	1.44	2.13	1.88	0.41	.528	
Not beginning bad news without preamble	2.13	2.07	2.00	1.77	4.20	1.08	1.73	1.98	20.50	< .001	X
Asking how much patient knows about his or her illness before breaking bad news	0.00	0.00	0.47	1.25	2.13	2.07	0.73	1.53	5.76	.024	
Not using technical words	2.93	1.49	2.73	1.58	3.60	1.30	3.07	1.22	1.23	.278	
Using actual images and test data	3.47	1.41	2.13	2.07	3.20	2.24	2.33	1.99	0.24	.629	
Writing on paper to explain	3.20	1.66	3.20	1.66	2.93	1.83	3.20	1.66	0.23	.636	
Checking to see that patient understands	2.27	1.83	2.13	1.81	3.13	1.92	1.20	1.70	8.33	0.008	
Checking to see whether talk is fast paced	0.53	1.13	0.33	0.90	1.67	2.29	0.00	0.00	9.29	.005	X
Communicating clearly main points of bad news	0.67	1.45	0.53	1.41	1.80	1.90	0.27	1.03	7.52	.011	
Discussing additional information	17.00	3.27	16.67	4.69	18.93	5.04	15.67	4.65	4.11	.053	
Answering patient's questions fully	4.00	0.00	3.60	0.91	4.07	0.26	3.73	0.59	0.98	.331	
Explaining status of patient's illness	3.73	0.46	3.73	0.46	3.80	0.41	3.47	1.06	2.32	.139	
Telling prospects of cancer cure	3.13	1.55	2.93	1.53	3.47	1.81	2.67	1.45	1.64	.211	
Providing information on services and support	0.33	1.05	0.53	1.41	0.27	1.03	0.27	1.03	11.15	.002	X
Discussing patient's everyday life and work in future	1.67	1.68	1.87	1.92	1.87	1.92	1.87	1.64	0.02	.963	
Explaining second opinion	0.27	1.03	0.27	1.03	1.33	1.95	0.00	0.00	7.27	.012	
Checking questions	3.87	0.52	3.73	0.70	4.13	0.52	3.67	0.72	4.40	.045	
Providing reassurance and addressing patient's emotions with empathic responses	18.67	5.91	15.33	7.19	22.53	7.81	13.80	7.17	7.45	.011	X
Asking about patient's worries and concerns	1.33	1.72	1.60	1.76	1.07	1.71	1.27	1.58	0.07	.796	
Using words to mentally prepare patient	3.53	1.13	1.07	1.67	3.47	1.41	0.80	1.42	0.32	.575	
Remaining silent out of concern for patient's feelings	0.47	1.13	1.27	1.53	2.20	1.78	0.67	1.45	9.59	.005	X
Accepting patient's expression of emotions	2.40	1.68	1.73	1.83	3.53	0.83	1.40	1.92	17.64	< .001	X
Using words that soothe patient	1.60	2.03	2.00	1.89	2.80	2.21	1.67	1.99	9.29	.005	X
Explaining in way that incorporates hope	3.93	0.26	3.13	1.55	3.60	1.12	3.27	1.22	1.11	.300	
Explaining what patient can hope for	4.00	0.00	3.07	1.33	3.87	0.52	3.40	1.18	0.78	.389	
Assuming responsibility for patient's care until end	1.40	1.50	1.47	1.64	2.00	2.17	1.33	1.76	1.40	.247	

Abbreviations: CG, control group; IG, intervention group; SD, standard deviation.
*Level of significance of each factor, $P < .013$; categories are as follows: setting up supportive environment for interview, $P < .017$; considering how to deliver bad news, $P < .006$; discussing additional information, $P < .007$; providing reassurance and addressing patient's emotions with empathic responses, $P < .006$.

Patients' Outcome Measure

Patients' distress. The Japanese version of HADS[21] was used to measure patients' distress.[22] The HADS is a self-administered and standardized instrument for evaluating patients' distress. It consists of 14 items grouped into two factors: anxiety (HADS-A, seven items) and depression (HADS-D, seven items). Each item is rated on a 4-point (0 to 3) Likert scale.

Patient satisfaction with consultation. Patient satisfaction with their oncologist's performance during consultation was assessed using an 11-point (0 to 10) numeric rating scale.

Patient trust in oncologist. Patient trust in their oncologist was assessed using an 11-point (0 to 10) numeric rating scale.

Statistical Analysis

The demographic characteristics of the oncologists and patients were compared among groups using the χ^2 or t test as required. Time change in the baseline and follow-up surveys of the factors and items related to oncologists' performance and the total score of oncologists' confidence questionnaires were analyzed using one-way analysis of variance (ANOVA) with controlled baseline data. Before ANOVA, Levene's test for equality of variances between groups (IG and CG) was used. Bonferroni correction was used to determine which items of oncologists' performance differed among the groups. For patients' outcome data (each factor of HADS, satisfaction, and trust) at the follow-up survey, we used generalized linear mixed models. The models included fixed effects for group (IG and CG) and the intercept and a random effect for clustering of patients within oncologists. The sample size was computed based on the main outcome: total RE scores (range, 8 to 80) of the SHARE model. On the basis of our previous study,[13] 13 oncologists per group were needed to detect a 6.2-point (standard deviation [SD], 5.5) change with power of 80% at $\alpha = 0.05$. Statistical significance was set at $P < .05$ for all analyses. The statistical analysis was performed using SPSS version 21.0 software (SPSS, Chicago, IL).

RESULTS

Oncologist Characteristics

Thirty (19.6%) of 153 oncologist candidates returned the consent form, whereas the others chose not to participate. Although there was no significant difference in specialty between the participants and nonparticipants ($\chi^2 = 0.76$; $P = .859$), there was a significant

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Table 3. Participant Characteristics

Characteristic	IG (n = 15) Median ± SD	IG (n = 15) Range	CG (n = 15) Median ± SD	CG (n = 15) Range	t	P
Age, years	38 ± 5.4	33-54	38 ± 5.5	35-50	−1.34	.192
Clinical experience, years	15 ± 5.3	9.3-30.3	14.5 ± 5.4	9.5-25.0	−1.17	.252
Clinical experience in oncology, years	10 ± 5.5	3.0-22.3	13.3 ± 6.1	6.1-25.0	−1.82	.080

	IG (n = 15) No.	IG (n = 15) %	CG (n = 15) No.	CG (n = 15) %	χ^2	P
Sex					0.00	1.000
Male	13	86.7	13	86.7		
Female	2	13.3	2	13.3		
Oncology specialty					1.06	.589
Surgical	9	60.0	8	53.3		
Medical	6	40.0	6	40.0		
Radiation	0	0.0	1	6.7		

Abbreviations: CG, control group; IG, intervention group; SD, standard deviation.

difference in sex ($\chi^2 = 6.31$; $P = .012$). The rate of participation among women (five of 11; 46%) was significantly higher than that among men. There was no significant difference in any participant characteristics between IG and CG (Table 3).

Performance of communication skills. For the 30 oncologists, we obtained evaluable videos of consultations in which bad news was relayed to an SP at baseline and follow-up. One-way ANOVA revealed significant differences in three of four factors and seven of 27 categories of SHARE (Table 2).

Confidence in communication with patients. There were significant differences by one-way ANOVA in the mean scores (± SD) of confidence in SHARE communication between the groups (IG: $\Delta = 22.5 \pm 34.4$; CG: $\Delta = -17.1 \pm 26.1$; $F = 13.7$; $P = .001$) and communication of bad news between the groups (IG: $\Delta = 19.2 \pm 19.6$; CG: $\Delta = -2.4 \pm 15.4$; $F = 11.2$; $P = .002$).

Patient Characteristics

In total, 1,181 of the 1,397 candidates who visited outpatient clinics were recruited to participate in the survey after consultation; 44 were excluded because of a physical or psychological problem, and 120 were not contacted because of refusal to participate or an inability to contact them. Of these 1,181, at baseline, 267 patients in the IG and 313 patients in the CG participated in the questionnaire survey; at follow-up, there were 292 patients in the IG and 309 patients in the CG (response rate, 84.6%). Thirteen to 32 patients were surveyed for each oncologist at baseline and follow-up. The correlation coefficient of the numbers at baseline and follow-up was $r = 0.60$ ($P < .001$). Patient characteristics at baseline and follow-up surveys, except for cancer type and current treatment status, were not significantly different between the IG and CG (Table 4).

Patient distress, satisfaction with consultation, and trust in oncologist. At the baseline survey, no score (± SD) was significantly different between the groups (HADS-A: mean, 5.48 ± 3.77 in IG; mean, 5.20 ± 3.79 in CG; HADS-D: mean, 5.20 ± 3.64 in IG; mean, 5.44 ± 4.30 in CG; HADS total: mean, 10.67 ± 6.82 in IG; mean, 10.65 ± 7.58 in CG; satisfaction with oncologist's communication: mean, 8.56 ± 1.68 in IG; mean, 8.44 ± 1.94 in CG; trust in oncologist: mean, 9.14 ± 1.40 in IG; and mean, 9.06 ± 1.64 in CG).

At the follow-up survey, the HADS-D score was significantly lower and the rating score of trust in oncologists was significantly higher for patients who met with oncologists from the IG compared with those of patients who met with oncologists from the CG. Conversely, there was no significant difference between these two groups regarding the HADS-A score, the HADS-total score, or patient satisfaction (Table 5).

DISCUSSION

To our knowledge, this is the first report to demonstrate the effect of CST on breaking bad news for oncologists in improving the psycho-

Table 4. Patient Characteristics at Follow-Up

Characteristic	IG (n = 292) No.	IG (n = 292) %	CG (n = 309) No.	CG (n = 309) %	χ^2	P
Age, years					0.29	.769
Median	64		64			
SD	10		10			
Male sex	179	61.3	190	61.5	0.00	.962
Employed	109	38.3	115	38.1	1.11	.576
Married	237	83.2	251	83.1	0.00	.979
Living alone	21	7.4	20	6.6	0.14	.714
Educational level ≤ 9 years	46	16.2	59	19.4	1.11	.293
Type of oncology specialist					21.47	< .001*
Surgical	193	66.1	175	56.6		
Medical	99	33.9	114	36.9		
Radiation	0	0.0	20	6.5		
Experience of bad news					2.89	.236
Cancer diagnosis	292	100.0	309	100.0		
Recurrence or metastasis	66	22.6	87	28.2		
Stopping anticancer treatment	0	0.0	0	0.0		
Currently receiving treatment	118	40.4	85	27.5	11.17	.001*
Consultation to deliver bad news	24	8.4	18	6.0	4.75	.093

Abbreviations: CG, control group; IG, intervention group; SD, standard deviation.
*$P < .01$

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Table 5. Comparison of Patient Psychological Distress, Perceived Communication, and Satisfaction Between Groups at Follow-Up

Factor	IG		CG		F	P
	Mean	SD	Mean	SD		
HADS						
Anxiety	4.83	3.75	5.17	3.42	0.94	.333
Depression	4.59	3.75	5.32	4.04	4.94	.027*
Total distress	9.36	6.93	10.50	6.90	3.85	.050
Satisfaction with oncologist communication	8.58	1.62	8.35	1.74	2.80	.095
Trust in oncologist	9.15	1.28	8.87	1.54	6.89	.009*

Abbreviations: CG, control group; HADS, Hospital Anxiety and Depression Scale; IG, intervention group; SD, standard deviation.
*$P < .05$.

logical distress of patients with cancer, as well as oncologist performance and confidence in communicating with patients, using a randomized design. Reasons for our positive results might include that the CST program had been developed based on patient preferences regarding the communication of bad news[11,12] and oncologists' needs.[17] Health professionals benefit by learning valuable communication strategies and reviewing the application of their skills in simulated clinical situations.[23] Hence, our study might have met these oncologists' needs and effectively helped them to provide more culturally appropriate support for their patients.

The results of the oncologists' performance and confidence showed that they had acquired emotional support skills after the CST, as in previous studies. Significant learning of new empathic skills occurred, including the use of silence and accepting a patient's expression of emotions, in contrast to the already well-established practices of offering hope, explaining the clinical findings, maintaining eye contact, and avoiding jargon. All communication skills dealt with in the CST program, such as the additional use of a preamble, checking the patient's current understanding of the illness, checking how well the news has been assimilated, and offering a second opinion, became new skills that enhanced oncologists' repertoire for dealing with difficult situations clinically. Interestingly, these increased performance skills did not prolong the consultation time. This result suggests the possibility that a patient's psychological distress can be reduced without increasing demands on oncologists in busy clinical practice.

These positive results might also have been influenced by the culture and attitude of Japanese patients and the basically poor support system for patients with cancer that currently exists in Japan. Although Japanese patients with cancer do not typically seek professional assistance for psychological problems caused by their cancer experience and usually repress their emotions about having cancer,[26] they need emotional support from their oncologists.[11,12,14] Improved communication behaviors among oncologists could thus alleviate the psychological distress of patients. This interpretation can be confirmed by the results of the oncologists' improved performance; that is, oncologists who participated in CST were more empathic.

This study showed that patients in the IG demonstrated less psychological distress and more trust in oncologists than those in the CG. However, we found no significant difference in the level of satisfaction of patients as a result of CST for oncologists.[27,28] The absence of such an effect suggests that a ceiling effect occurred for satisfaction scores in this study. Specifically, 61% of patients gave the maximum satisfaction score. Patient satisfaction studies generally report a high level of satisfaction,[26] which is taken to indicate a high quality of service. However, some patients may be afraid of hurting their oncologists' feelings if they express dissatisfaction with their health care. This can be a particular concern for patients with cancer in view of the potentially life-threatening nature of their illness.[28] Another problem has also been suggested regarding the validity of tools used to measure satisfaction.[29] In particular, few questionnaires are visit specific or deal with just one physician rather than the entire experience of visiting a hospital.[5]

Some limitations of this study should be noted. First, the rate of participation here was only approximately 20% of recruited senior oncologists from two institutions, both comprehensive cancer center hospitals. However, this is not particularly low, because recruitment for this kind of intervention study is difficult, as described in previous studies.[23,30,31] Although there was a sex difference in the rate of participation, women numbered only 11 (7.2%) of the 153 oncologists. We could also not obtain any other data on the oncologists who declined to participate, besides their specialty and sex. The identification of oncologists' demographic factors associated with participation in the CST might be important when applying the CST program to a medical education setting. Furthermore, this study has only shown the positive effects of the CST on subjective and objective measurements of oncologists' communication skills for experienced attendees with extensive experience of oncology in a comprehensive cancer center. However, medical students or residents might be expected to benefit more from participation in CST than highly skilled oncologists, such as those in this study. Second, this study showed only short-term effects and did not evaluate the long-term effects on oncologists. However, previous studies have shown that oncologists who participated in a CST workshop maintained their communication skills at a high level 1 year later, but future studies need to evaluate the long-term effects. Third, this study included patients who were newly diagnosed as well as patients participating in follow-up visits; however, this is realistic for identifying the effects of a CST program on actual patient outcomes in a clinical context.

Although additional studies are needed to resolve these limitations, this work shows that communication skills that comply with patient preferences can be taught to oncologists, and their use decreases patient distress. Our study might thus provide encouragement and a direction for future research in the application of CST for more health professionals in oncologic practice to help oncologists deal with unrecognized distress among patients diagnosed with cancer.

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

The author(s) indicated no potential conflicts of interest.

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Financial support: Yosuke Uchitomi
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