



Out-of-pocket expenditure burdens in patients with cardiovascular conditions and psychological distress: a nationwide cross-sectional study

Yasuyuki Okumura, Ph.D.^{*}, Hiroto Ito, Ph.D.

Department of Social Psychiatry, National Institute of Mental Health, National Center of Neurology and Psychiatry, Tokyo 187-8553, Japan

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ABSTRACT

Objectives: This study aimed to estimate the prevalence of psychological distress in individuals with and without cardiovascular risks and events [cardiovascular disease (CVD) conditions] and the incremental effects of psychological distress on the out-of-pocket health care expenditure burdens.

Methods: We used data from the Comprehensive Survey of Living Conditions 2007, a nationally representative cross-sectional survey in Japan. Psychological distress assessed by the K6 scale, the presence of treated CVD conditions and out-of-pocket health care expenditures as a share of household consumption expenditures were self-reported by 20,763 individuals living alone and aged between 20 and 59 years.

Results: Individuals with obesity [adjusted odds ratio (AOR), 4.3], stroke (AOR, 3.2), ischemic heart disease (AOR, 2.3), hyperlipidemia (AOR, 1.8) or diabetes (AOR, 1.7) were more likely than those without to have serious psychological distress (SPD). With the exception of ischemic heart disease, less than half of CVD patients comorbid with SPD received treatment for mental illness. Patients comorbid with SPD and obesity (AOR, 6.1), SPD and ischemic heart disease (AOR, 3.4), and SPD and hypertension (AOR, 2.6) had higher out-of-pocket burdens than patients with only CVD conditions.

Conclusions: Our findings suggest the need for physicians to identify and manage SPD in patients with CVD conditions and for policymakers to find solutions to reduce the high out-of-pocket burdens among these patients.

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1. Introduction

Cardiovascular risks and events [cardiovascular disease (CVD) conditions] such as obesity, hyperlipidemia, hypertension, diabetes, ischemic heart disease and stroke have been major public health concerns around the world [1]. Individuals with CVD conditions are about twice as likely to suffer from depression, anxiety and psychological distress as those without the conditions [2–4]. These comorbidities remain significant individual and public health concerns because they lead to poor quality of life [4], nonadherence to cardiac medication [5], excess direct medical costs [6], productivity loss due to absence from work [7] and increased mortality [8].

Available evidence on comorbidities of CVD conditions with psychological distress and their negative consequences has several limitations. First, few studies, most of which were conducted in the United States, have used nationally representative samples to establish unique associations between the presence of psychological distress and particular CVD conditions [3,9–14]. Second, it remains

uncertain whether comorbidities of CVD conditions with psychological distress are associated with burdens of out-of-pocket health care expenditures relative to effective income. Identifying high out-of-pocket burdens is important because these burdens may be associated with delaying or foregoing medical care for financial reasons [15], which in turn may lead to severe health conditions. Generally, out-of-pocket burden in Japan is lower than other countries [16] because Japan has a universal health care system that reduces out-of-pocket health care expenditures to less than 30% of medical fees. Even in countries where health care systems provide excellent population health at low cost with equity [17], we hypothesized that there would be an incremental effects of psychological distress on out-of-pocket burdens because psychological distress leads to excess direct medical costs and productivity loss [6,7].

In the present study, we used data from a nationally representative sample of 20- to 59-year-old individuals living alone. We had two specific objectives for the present study. First, we examined whether the prevalence of psychological distress was higher in individuals with CVD conditions than in those without CVD conditions. Second, we examined whether out-of-pocket health care expenditures as a share of household consumption expenditures were higher in individuals with psychological distress than in those without.

2. Methods

2.1. Data source

We used data from the Comprehensive Survey of Living Conditions (CSLC) 2007, a nationally representative cross-sectional survey of Japanese-speaking household members in Japan, conducted by the Ministry of Health, Labour and Welfare between June and July 2007 [18]. In the present study, we obtained permission to use data by the Ministry of Health, Labour and Welfare. The CSLC assessment has three parts: (a) the Household and Health questionnaires for the entire sample, (b) the Income and Savings questionnaires for the subsample and (c) the Long-term care questionnaire for the subsample. A detailed description of the CSLC has been reported previously [18–20]. Only data from the Household and Health questionnaires were used for the present study and reported below.

The target population of the CSLC comprised a total of ≥ 120 million individuals in Japan. Of about 940,000 enumeration districts delineated to comprise 50 households per enumeration district in the 2005 Population Census [21], 5440 were selected by a stratified random sampling method. All members were recruited from 287,807 households within the enumeration districts. A total of 624,168 members in 229,821 households answered the questionnaires (response rate, 79.9%).

In the present study, we used a subsample comprising 20,736 participants living alone who were aged between 20 and 59 years and noninstitutionalized and who completed questions on working status, out-of-pocket health care expenditure and household consumption expenditure (Figure). We focused only on individuals living alone to measure individual out-of-pocket health care expenditures that were not shared by financial resources of other family members. In addition, we restricted samples to working-age adults for the following reasons. First, individuals aged ≥ 60 years are more likely to receive retirement benefits and public pension, which can provide

regular effective income irrespective of disability status. Second, Japan's universal health care system pays 70% of medical fees charged to most individuals aged ≤ 69 years and 90% to most individuals aged ≥ 70 years. Including those over 59 years would decrease the comparability of out-of-pocket burdens between working-age and elderly adults.

2.2. Measures

2.2.1. Current treated CVD conditions

Current treated medical conditions were assessed with a self-report checklist that included 41 conditions such as diabetes and obesity. Respondents were asked to report whether they were currently being treated for any condition in a noninstitutionalized setting, mark all conditions listed in the checklist and indicate the most worrisome condition. Such checklists have been widely used in prior population-based studies [22,23]. Our report considers only the status of each condition rather than the most worrisome condition. Of the 41 conditions, we selected the following seven highly related cardiovascular risks and events as in previous studies [24,25]: (a) diabetes, (b) obesity, (c) hyperlipidemia, (d) hypertension, (e) stroke, (f) ischemic heart diseases and (g) other CVDs.

2.2.2. Treatment status of mental illness

As mentioned above, current treated medical conditions were assessed with the self-report checklist. We coded whether participants received treatment for mental illness using the item 'depression or other mental illness' in the checklist.

2.2.3. Psychological distress

The CSLC assesses nonspecific psychological distress using the K6 scale [26,27]. The K6 is a self-rated six-item questionnaire that asks respondents how frequently they have experienced symptoms of psychological distress during the past 30 days (e.g., 'During the past

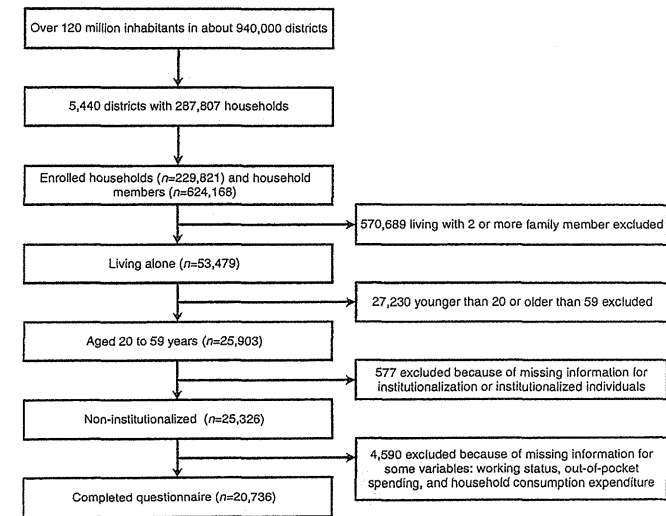


Fig. Flow diagram of included and excluded participants.

^{*} Corresponding author. Tel.: +81 42 346 2046; fax: +81 42 346 2047.
E-mail address: yokumura@ncnp.go.jp (Y. Okumura).

30 days, about how often did you feel nervous?). Respondents rate each question on a five-point scale ranging from 'none of the time' (0) to 'all of the time' (4). The K6 scores range from 0 to 24, with higher scores indicating more severe psychological distress. Based on a previous validation study [27], the K6 scores were classified into four mutually exclusive groups: (a) a probable serious psychological distress (SPD) group defined as a score on the K6 of 14–24, (b) probable mild/moderate psychological distress (MPD) group defined as the K6 of 9–13, (c) probable noncase group defined as the K6 of 0–8 and (d) an unknown group defined as one with any missing values. Although most previous studies have focused only on SPD [3,9–14], we consider it important to examine MPD as well as SPD because of the high rates of hospitalization, work disability, suicide attempts and subsequent SPD [28].

2.2.4. Out-of-pocket expenditure burdens

Respondents were asked about their out-of-pocket health care expenditures in the past month. It included all direct medical costs such as physical examinations, medical treatments and pharmaceuticals: It did not include cash outlays for nursing care, payments for health insurance premiums or direct nonmedical costs such as transportation and parking. Respondents were also asked about their household consumption expenditures in the past month. It included all payments for goods and services, but excluded expenditures that did not translate directly into acquisition of goods and services such as tax, pension and health insurance premiums. Consumption expenditures have been widely used as a proxy for effective income in prior studies [29,30]. We created a variable by dividing out-of-pocket health care expenditures by household consumption expenditures.

2.2.5. Sociodemographic characteristics

The respondents' sociodemographic characteristics included gender, age, marital status, employment status, pension status and urbanicity. Age was divided into four categories (20–29, 30–39, 40–49 and 50–59 years). Marital status was categorized as married, single and widowed/divorced. Urbanicity was divided into major metropolitan area, other urbanized area and rural area.

2.3. Statistical analyses

We used bivariate and multivariate multinomial logit models to examine associations between treated CVD conditions and psychological distress [31]. The outcome variable was the status of psychological distress: (a) probable SPD group, (b) probable MPD group, (c) probable noncase group (the reference group) and (d) the unknown group. The primary explanatory variables were individual CVD conditions. We estimated odds ratios (ORs) and their 95% confidence intervals (CIs) for the SPD and MPD groups compared with the noncase group after simultaneously controlling for potential confounders. The potential confounding variables included in the models were selected based on a priori clinical knowledge and existing literature [2–4] as follows: (a) gender, (b) age, (c) marital status, (d) employment status, (e) pension status and (f) urbanicity. In addition, we estimated the ratios of treated mental illness using data available for both CVD conditions and psychological distress.

We also investigated the association between psychological distress and out-of-pocket expenditure burdens. We used bivariate and multivariate generalized linear models with the log link function and variance proportional to the mean [32,33]. The outcome variable was out-of-pocket expenditures with the natural logarithm of household consumption expenditures included in the model as an offset term. The primary explanatory variable was the status of psychological distress. Estimated coefficients were exponentiated to

provide ratios of out-of-pocket burdens for each CVD condition. Because of the known interactions of individual CVD conditions and psychological distress on functional disability [34], all analyses were stratified by individual CVD conditions. The potential confounding variables in the models were selected a priori clinical knowledge and epidemiological evidence [6,7] as follows: (a) gender, (b) age, (c) marital status, (d) employment status, (e) pension status, (f) urbanicity and (g) number of CVD conditions.

Significance levels were set at 5% for all analyses. Data were analyzed using R version 2.15.1 [35].

3. Results

3.1. Participants

Table 1 shows the characteristics for 20,736 participants. The median age was 38 years (interquartile range, 27–57 years). Of the participants, 61.5% were men, 10.3% were married, 85.1% were

Table 1 Sociodemographic, cardiovascular risks and events, and psychological distress of participants

Characteristic	Total (N=20,736)	
	n	%
Gender		
Men	12,760	61.5
Women	7,976	38.5
Age, years		
20–29	6,336	30.6
30–39	4,632	22.3
40–49	3,655	17.6
50–59	6,113	29.5
Marital status		
Married	2,134	10.3
Single	14,421	69.5
Widowed/divorced	4,181	20.2
Employment status		
Employed	17,641	85.1
Unemployed	3,095	14.9
Pension status		
Without	20,169	97.3
With	567	2.7
Urbanicity		
Major metropolitan area	5,006	24.1
Other urbanized area	13,995	67.5
Rural area	1,735	8.4
Number of CVD conditions		
0	19,136	92.3
1	1,187	5.7
≥2	413	2.0
Type of CVD conditions		
Diabetes	441	2.1
Obesity	59	0.3
Hyperlipidemia	427	2.1
Hypertension	893	4.3
Stroke	97	0.5
Ischemic heart disease	110	0.5
Other cardiovascular diseases	123	0.6
Psychological distress (scores on the K6) ^a		
SPD (≥14)	1,126	5.4
MPD (9–13)	2,425	11.7
Noncase (0–8)	15,838	76.4
Unknown	1,347	6.5
OOP burdens		
0%	13,932	67.2
0.1%–1.9%	2,245	10.8
2%–4.9%	2,235	10.8
5%–9.9%	1,345	6.5
≥10%	979	4.7

OOP burdens, out-of-pocket health care expenditures as a share of household consumption expenditures.

^a SPD group was defined as K6 scores of ≥14, MPD group as 9–13, noncase group as 0–8 and unknown group as any missing values.

Table 2 Multinomial logistic analyses examining the comorbidities of treated cardiovascular risks and events with psychological distress

CVD conditions	n	Prevalence, %		Crude OR ^{a,b} (95% CI)		AOR ^{a,b,c} (95% CI)	
		SPD	MPD	SPD	MPD	SPD	MPD
Diabetes							
With	441	6.5	12.5	1.33 (0.91–1.96)	1.17 (0.88–1.56)	1.66 (1.11–2.46)*	1.38 (1.02–1.85)*
Without	20,295	5.4	11.7	1	1	1	1
Obesity							
With	59	16.9	11.9	3.93 (1.95–7.95)*	1.27 (0.56–2.86)	4.31 (2.10–8.82)*	1.41 (0.63–3.19)
Without	20,677	5.4	11.7	1	1	1	1
Hyperlipidemia							
With	427	7.0	12.9	1.42 (0.97–2.07)	1.20 (0.90–1.61)	1.82 (1.23–2.69)*	1.43 (1.06–1.92)*
Without	20,309	5.4	11.7	1	1	1	1
Hypertension							
With	893	4.5	11.1	0.91 (0.66–1.26)	1.06 (0.85–1.31)	1.22 (0.87–1.70)	1.29 (1.03–1.61)*
Without	19,843	5.5	11.7	1	1	1	1
Stroke							
With	97	11.3	15.5	2.94 (1.53–5.64)*	1.85 (1.04–3.29)*	3.16 (1.62–6.13)*	2.04 (1.14–3.64)*
Without	20,639	5.4	11.7	1	1	1	1
Ischemic heart disease							
With	110	8.2	12.7	1.93 (0.96–3.87)	1.39 (0.78–2.47)	2.29 (1.12–4.66)*	1.60 (0.90–2.88)
Without	20,626	5.4	11.7	1	1	1	1
Other cardiovascular							
With	123	5.7	17.1	1.41 (0.65–3.07)	1.97 (1.21–3.21)*	1.57 (0.72–3.45)	2.18 (1.33–3.57)*
Without	20,613	5.4	11.7	1	1	1	1

^a The reference groups for primary independent variables were defined as individuals without each CVD condition.

^b The reference groups for dependent variables were defined as a score on the K6 of 0–8.

^c ORs after simultaneously controlling for potential confounders that were gender, age, marital status, employment status, pension status and urbanicity.

* P<.05.

employed, and 2.7% received disability, survivor or public pensions. Hypertension (4.3%), diabetes (2.1%) and hyperlipidemia (2.1%) were the most prevalent among specific CVD conditions. The average out-of-pocket burden was 2.1% (S.D., 6.2%). Of the participants, 4.7% had out-of-pocket health care expenditures exceeding 10% of household consumption expenditures.

3.2. Prevalence of psychological distress

The prevalence ratios for SPD and MPD were estimated to be 5.4% and 11.7% in all participants. Among specific CVD conditions, individuals with obesity [adjusted odds ratio (AOR), 4.3; 95% CI, 2.1–8.8], stroke (AOR, 3.2; 95% CI, 1.6–6.1), ischemic heart disease (AOR, 2.3; 95% CI 1.1–4.7), hyperlipidemia (AOR, 1.8; 95% CI, 1.2–2.7) or diabetes (AOR, 1.7; 95% CI, 1.1–2.5) were more likely to have SPD compared with those without each CVD condition (Table 2). With the exception of ischemic heart disease, less than half of CVD patients comorbid with SPD received treatment for mental illness (Table 3).

3.3. Psychological distress and out-of-pocket expenditure burdens

Table 4 shows out-of-pocket health care expenditures as a share of household consumption expenditures by individual CVD conditions.

Table 3 Ratios of treated mental illness in patients comorbid with CVD conditions and psychological distress

CVD conditions	Ratios of treated mental illness, % (95% CI)	
	SPD	MPD
Diabetes	31.0 (15.3–50.8)	12.7 (5.3–24.5)
Obesity	40.0 (12.2–73.8)	14.3 (0.4–57.9)
Hyperlipidemia	50.0 (31.3–68.7)	20.0 (10.4–33.0)
Hypertension	30.0 (16.6–46.5)	10.1 (5.0–17.8)
Stroke	0.0 (0.0–38.5)	0.0 (0.0–30.2)
Ischemic heart disease	55.6 (21.2–86.3)	14.3 (1.8–42.8)
Other cardiovascular	42.9 (9.9–81.6)	14.3 (3.0–36.3)

For example, average out-of-pocket burdens for SPD, MPD and noncase groups were estimated to be 11.3%, 4.8% and 6.4% among individuals with diabetes and 3.6%, 2.5% and 1.7% among individuals without diabetes, respectively. Among specific CVD conditions, patients comorbid with SPD and obesity (AOR, 6.1; 95% CI, 2.1–16.6), SPD and ischemic heart disease (AOR, 3.4; 95% CI, 1.3–8.5), and SPD and hypertension (AOR, 2.6; 95% CI, 1.6–4.0) had higher out-of-pocket expenditure burdens than patients with only CVD conditions. In comparison, no significant differences in burdens were observed between CVD patients comorbid with MPD and patients with only CVD conditions. Among individuals without each CVD conditions, SPD and MPD groups had higher out-of-pocket burdens than noncase group.

4. Discussion

This cross-sectional study of a nationally representative sample of Japanese noninstitutionalized 20- to 59-year-old individuals living alone had two major findings. First, the prevalence ratios for SPD were over 1.6 times higher in individuals with obesity, stroke, ischemic heart disease, hyperlipidemia or diabetes than in those without each CVD condition after controlling for potential confounders. Second, average out-of-pocket burdens were over 2.5 times higher in patients comorbid with SPD and obesity, SPD and ischemic heart disease, and SPD and hypertension than in those with only CVD conditions.

Consistent with previous findings, we found associations between the presence of psychological distress and obesity [12], stroke [11,12], ischemic heart disease [11–13], hyperlipidemia [12] and diabetes [12,13]. In addition, we found that less than half of CVD patients comorbid with SPD received treatment for mental illness, with the exception of ischemic heart disease. These results confirm the need for identifying and managing psychological distress in patients with CVD conditions [36,37].

Comorbidities of obesity, ischemic heart disease or hypertension with SPD lead to excess out-of-pocket health care expenditure burdens. Several potential explanations account for the high out-of-pocket burdens among CVD patients comorbid with SPD. First,

Table 4
Screening performance of the categorical algorithms of the PHQ-9 and PHQ-2

	Se	Sp	PPV	NPV	OR	LR+	LR-
PHQ-9	0.42	1.00	0.93	0.96	308.5	178.7	0.58
PHQ-2	0.77	0.91	0.40	0.98	32.5	8.37	0.26

of patients, the percentage of patients who would be erroneously overdiagnosed as having depression would now be only 4.6%. Given the risk of overdiagnosis, the cutoff point 7/8 of the PHQ-9 may be more useful than the cutoff point 4/5. In a different context, the cutoff point 10/11, the specificity and the PPV for which were 0.99 and 0.76, respectively, may be more useful so as not to overdiagnose depression in routine clinical practices.

For patients in an internal medicine outpatient clinic in a rural general hospital in Japan, the categorical algorithm of the PHQ-9 had lower sensitivity, whereas the higher specificity seems to be excessive given the cost of overlooking a significant proportion of depressed patients. Meanwhile, the PHQ-2 had adequate sensitivity and specificity. In such an internal medicine outpatient clinic, the PPV of 0.40 and the NPV of 0.98 of the PHQ-2 may be acceptable. In a setting where the prevalence of depression was 7.4% [25], the PHQ-9 overlooked about 58% of patients with major depressive disorders, while the PHQ-2 overlooked about 23% of those. However, the PHQ-2 overdiagnosed 8.3% of patients without major depressive disorders as having depression. Thus, follow-up clinical diagnosis or follow-up monitoring is needed to exclude these pseudopositive patients as not having a depression diagnosis.

Previous studies showing sensitivity and specificity of the PHQ-9 among Korean people and/or the elderly showed a lower score as the cutoff point, such as 4/5 and 6/7 [16,17]. Thus, the elderly, especially in Asian populations, may hesitate to express their depressive symptoms in a self-reported questionnaire. The World Health Organization and the World Psychiatric Association have stated that depression in old age is stigmatized in several ways [41], and the stigmatization against depression in elderly people may cause them to underreport their depressive symptoms as discussed in a previous study [17]. Other studies discussed different reasons, such as that the elderly generally focus on somatic rather than cognitive and emotional symptoms and thus the PHQ-9 may not fully recognize the core features of depression [16].

The sensitivity of the PHQ-9 categorical algorithm as shown in the present study was lower than that in previous meta-analyses including primary care and general practice settings [10,12,14]. Lower sensitivities of the PHQ-9 categorical algorithm were shown in a study among inpatients in a hospital department of internal medicine in Geneva, Switzerland [22]; among chronically ill elderly patients in general practices in Limburg, a province in the Netherlands [17]; and among patients with medical disorders in Spain [23]. These previous studies showing lower sensitivities of the PHQ-9 categorical algorithm were all targeting patients with physical illness. Considering that the PHQ-9 included vegetative symptoms, such as appetite loss and fatigue, patients with chronic illness may have attributed their depressive symptoms to their physical conditions and not to their depressive disorder, as discussed in the previous study [22]. Although we have no data and have no clear-cut explanation for it,

Table 5
Performance of item #9 of the PHQ-9 in screening for suicidality

	Se	Sp	PPV	NPV	OR	LR+	LR-
Score of item #9 of PHQ-9							
0/1	0.70	0.97	0.76	0.96	70.60	21.99	0.31
1/2	0.17	1.00	1.00	0.89	-	-	0.83
2/3	0.13	1.00	1.00	0.89	-	-	0.87

“-”: Because these are cells with zero, it is impossible to estimate the value.

patients with physical illness may be apt to recognize their vegetative depressive symptoms as symptoms of their physical illness and may respond to the vegetative symptom items as “none” even though they are present.

Item #9 of the PHQ-9, which asks about current suicidality, had applicable validity, given the sensitivity and specificity of 0.70 and 0.97, respectively, in screening for suicidality. The values were not so different from those reported in a previous study among depressed primary care patients (sensitivity: 0.84; specificity: 0.69), which were calculated using the suicide item in the mood module of the Structured Clinical Interview for DSM-IV Axis I Disorders [42]. Meanwhile, the PHQ-2 missed more than 60% of patients who endorsed item #9 of the PHQ-9. Administration of only the two questions included in the PHQ-2 may not be sufficient to identify such patients. This study suggests that the routine use of the PHQ-9 or PHQ-2 plus item #9 of the PHQ-9 would be recommended to identify individuals at risk for suicide who would not otherwise have been identified.

In the present study, we calculated the SSLRs [40] of the PHQ-9. Our previous study showed the estimated prevalence of major depressive episodes was 7.4% in a general internal medicine polyclinic in rural Japan [25]. The physician working at the clinic has information that those with a score ≥ 10 have a 65% chance of having depression based on the SSLR=23.1, while those whose scores are 0–4 (SSLR=0.16) have only a 1% chance of having depression. This information is more useful than adopting the single recommended threshold.

The study has several limitations. First, we selected only a single hospital located in a rural area for convenience. The findings of the present study can be generalized to outpatients in general internal medicine in Japanese rural hospitals, where patients are generally elderly and have chronic physical illness. However, this population may not be representative of other populations in Japan, such as those in urban hospitals and those in specific outpatient clinics. A survey of multiple, randomly selected sites from across Japan should be performed to generalize the findings. Second, the number of subjects was relatively small. Third, the present study used the MINI. Although the MINI is a validated interview tool to diagnose psychiatric disorders, a semistructured interview for DSM-IV may have been more appropriate. In a validation study of the Japanese version of the MINI using the structured clinical interview for DSM-III-R [31], the sensitivity and specificity to detect major depression were 1.0 and 0.87, respectively, suggesting the MINI may overlook a segment of those patients with major depression. This may have caused the apparent low sensitivity of the PHQ-9 and is one of limitations of the present study.

In conclusion, the PHQ-2 may be preferred in screening for patients with major depression in internal medicine outpatient clinics of rural general hospitals in Japan from the viewpoint of validity and ease of use. However, performing only the PHQ-2 may miss many suicidal patients. Given that item #9 of the PHQ-9 can detect suicidality, performing the PHQ-2 plus item #9 of the PHQ-9 is recommended.

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Table 1
Characteristics of participants

Characteristics	n=511
Age	Mean (S.D.) years old 73.5 (12.3) Median (range) years old 75 (21–102)
Sex (male): n, %	n=208 40.7%
Clinical diagnosis of primary illness: n, %	
Hypertension	n=300 58.7%
Diabetes	n=82 16.0%
Hyperlipidemia	n=81 15.9%
Brain infarction	n=43 8.4%
Arrhythmia	n=35 6.8%
Number of visits in the past 6 months: median (range)	4 (0–74)
Patients diagnosed as having major depressive episode by MINI: n, %	n=37 7.4%
Patients assessed as having current suicidality by MINI: n, %	n=65 12.7%

Additional detailed information has been reported previously [25].

Structured Clinical Interview for DSM-III-R in the previous study [31]. Additionally, we assessed risk of suicide using the Suicide module of the MINI.

2.3. Procedure

We adopted a random sampling stratified by the PHQ-9 results [36]. We used the following two criteria to stratify patients to receive the next step of the MINI interview session as “probable depression”: more than two items were present, of which one item was either of the first two items in the PHQ-9 (item 1: anhedonia or item 2: depressed mood), or the score of the dimensional assessment of the PHQ-9 was more than 10. Trained psychiatrists (M.I. or M.Y.), who were blind to the results of the PHQ-9, conducted semistructured MINI interviews of patients who met either of the two criteria and of patients who were randomly selected from among those who did not meet either of the two criteria [36,37]. The MINI interviews were performed after the PHQ-9 screening in a different room on the same day. The interval between the MINI interview and the PHQ-9 was approximately 120 min, depending on the availability of the room and the interviewers and on the timing of participants’ routine clinical consultation with internal medical physicians.

We defined the target population to estimate the validity of the PHQ-9 and the PHQ-2 by the inclusion criteria described in the participant section.

2.4. Statistical analysis

We calculated the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), odds ratio, likelihood ratio of a positive test and likelihood ratio of a negative test of the categorical algorithm of the PHQ-9 and the PHQ-2 using sampling weights [36,37] with multiple imputations for the missing data [38]. The weight was based on the inverse of the sampling probability for age, sex, clinical diagnosis of primary illness and PHQ-9 dimensional score. In this way, we estimated the point values and the 95% confidence intervals (CIs) of the screening indices statistically in the targeted population of 511 outpatients.

In addition to the categorical algorithms, we calculated the same values for the dimensional assessment of the PHQ-9 using various cutoff points. For the dimensional scores of the PHQ-9 and the PHQ-2, we illustrated the receiver operating characteristic (ROC) curves, calculating the area under the curves (AUC). Cutoff points based on the Youden index [39] were determined.

We calculated stratum-specific likelihood ratios (SSLRs) [40] of the PHQ-9 dimensional score. The cutoff thresholds recommended in the literature for the PHQ-9 were 4/5 for mild depression and 9/10 for moderate to severe depression [15,30]. Thus, we calculated SSLRs for the PHQ-9 for the scores 0–4, 5–9 and 10 and over.

We estimated the validity of item #9 of the PHQ-9 to detect current suicidality as measured by the MINI suicidal module. Then, as a supplemental analysis, to confirm whether the PHQ-2 would miss suicidality or not, we showed the sensitivity, specificity and other indices of the PHQ-2 to screen for suicidality as measured by item #9 of the PHQ-9.

We performed all statistical analyses using the statistical software packages SPSS 17.0 (IBM, Tokyo, Japan) and Statistical Analysis System (SAS) 9.2 (SAS Institute, Tokyo, Japan).

3. Results

3.1. Sampling process

The results of the sampling process have been reported in our previous study [25]. During the study period, 598 patients visited the clinic. We randomly selected 107 of the outpatients. From the selected 107 patients, we excluded 21 based on our inclusion criteria: 1 was less than 20 years old, 7 consulted family members, 1 resided outside the area, and 12 were severely cognitively impaired. Among the 86 patients, 5 patients were physically too ill, and 1 refused to participate in the study. Then, we administered the PHQ-9 to 80 patients who agreed to participate in the survey.

Among the remaining 491 patients who were not selected randomly, we excluded 66 based on our inclusion criteria: 16 were less than 20 years old, 15 consulted for family members, 1 visited to prepare for admission, 2 resided outside the area, and 32 were severely cognitively impaired. Among the 425 patients, 12 were physically too ill, 4 were missed, and 5 refused to participate in the study. Then, we administered the PHQ-9 to 404 patients and acquired PHQ-9 data for 396 of the 404 patients, with eight sets of PHQ-9 data being incomplete. As a result, 36 patients out of the 396 were screened as positive for probable depression.

Among the total 116 participants (80 and 36 participants), 104 received a structured interview using the MINI. Twelve patients were not interviewed (seven were missed, one was physically ill, and four refused the interview).

The target population to estimate prevalence was 511 patients (86 and 425 patients).

Table 2
Screening performance of the dimensional assessments of the PHQ-9 and PHQ-2

	Se	Sp	PPV	NPV	OR	LR+	LR-
PHQ-9 cutoff point							
3/4	0.86	0.80	0.26	0.99	25.37	4.31	0.17
4/5	0.86	0.85	0.32	0.99	36.9	5.88	0.16
5/6	0.67	0.90	0.35	0.97	18.08	6.69	0.37
6/7	0.67	0.93	0.42	0.97	25.76	9.25	0.36
7/8	0.67	0.95	0.53	0.97	39.96	13.99	0.35
8/9	0.55	0.96	0.53	0.96	29.88	14.08	0.47
9/10	0.55	0.98	0.65	0.96	50.0	23.2	0.46
10/11	0.45	0.99	0.72	0.96	59.36	32.84	0.55
11/12	0.45	0.99	0.82	0.96	105.87	58.21	0.55
12/13	0.37	1.00	0.86	0.95	124.68	78.33	0.63
PHQ-2 cutoff point							
1/2	0.77	0.89	0.36	0.98	26.77	6.97	0.26
2/3	0.77	0.95	0.54	0.98	60.61	14.81	0.24
3/4	0.61	0.98	0.66	0.97	62.30	24.75	0.40
4/5	0.31	1.00	0.90	0.95	162.32	112.72	0.69

Se, sensitivity; Sp, specificity; OR, odds ratio; LR+, likelihood ratio of positive test; LR-, likelihood ratio of negative test.

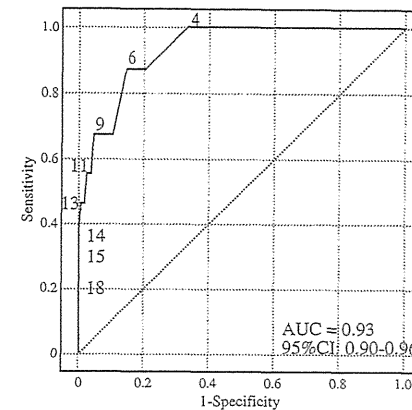


Fig. 1. ROC curve and AUC of the PHQ-9.

3.2. Participants' characteristics

The characteristics of the 511 subjects who were the target population to estimate the validity of the PHQ-9 and the PHQ-2 were reported in a previous study [25]. Table 1 summarizes the characteristics of the participants.

3.3. Dimensional assessment of the PHQ-9 and PHQ-2

Table 2 shows the results of the sensitivity, specificity, PPV, NPV, odds ratio, likelihood ratio of a positive test and likelihood ratio of a negative test using each of the cutoff points of the PHQ-9 and the PHQ-2. It was shown that the cutoff point of the PHQ-9 determined by the Youden index was 4/5 and the cutoff point of the PHQ-2 determined by the Youden index was 2/3 (Table 2).

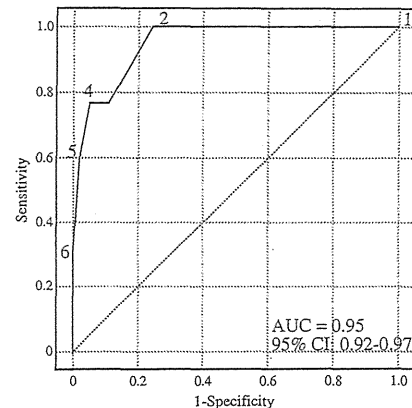


Fig. 2. ROC curve and AUC of the PHQ-2.

ROC curves of the PHQ-9 and the PHQ-2 are displayed in Figs. 1 and 2. The AUC of the PHQ-9 was 0.93 (95% CI: 0.90–0.96), and that of the PHQ-2 was 0.95 (95% CI: 0.92–0.97).

The SSLRs with their 95% CIs of the PHQ-9 weighted back to the target population are shown in Table 3.

3.4. Categorical algorithm of the PHQ-9 and PHQ-2

Using the categorical algorithm of the PHQ-9 and PHQ-2, the sensitivity, specificity, PPV, NPV, odds ratio, likelihood ratio of a positive test and likelihood ratio of a negative test are shown in Table 4.

3.5. PHQ-9 item #9 (suicidality)

The estimated sensitivity, specificity, PPV, NPV, odds ratio, likelihood ratio of a positive test and likelihood ratio of a negative test of the PHQ-9 item #9 (suicidality) for detecting suicidality as measured by the MINI are shown in Table 5. The cutoff score of 0/1 of item #9 of the PHQ-9 showed good sensitivity (0.70) and specificity (0.97) (Table 5).

Among the 476 patients who completed the PHQ-9, 54 patients (11.3%) endorsed item #9 of the PHQ-9 (suicidality). Among the 54 patients, the PHQ-2 categorical assessment for depression screened 21 patients as probably depressed. However, the PHQ-2 did not pick up the remaining 33 patients with probable suicidality (61.1% of the 54 patients with probable suicidality as judged by item #9 of the PHQ-9), suggesting that many suicidal patients would be missed without performing item #9 of the PHQ-9.

4. Discussion

In the present study, the validity of the Japanese version of PHQ-9 and PHQ-2 was examined. Compared with the results of the categorical assessment of the PHQ-9, the PHQ-2 and the dimensional algorithm using a cutoff point of 4/5 on the PHQ-9 had preferable sensitivity and specificity in screening for major depressive disorders.

Using the cutoff point of 9/10 recommended in previous publications [15,30], the sensitivity of the dimensional assessment of the PHQ-9 was low. The cutoff point 4/5, which was a cutoff point determined by the Youden index for the subjects of the present study, was more adequate. However, even using the cutoff point of 4/5, 14% of depressed patients were overlooked and 15% of nondepressed patients were overdiagnosed as having depression. Comparing the PHQ-2 and the dimensional algorithm of the PHQ-9 with a cutoff point of 4/5, the PHQ-9 with cutoff point 4/5 had a preferable sensitivity but a lower specificity. Given the small differences in sensitivities and specificities between the PHQ-2 and the PHQ-9 with a 4/5 cutoff point and given the simplicity of the evaluation, the PHQ-2 may be preferred in screening for depression in this setting.

However, applying the cutoff point 4/5 would lead to overdiagnoses, as more than 13% of patients would be erroneously judged to have depression in a setting where the prevalence of depression was 7.4% [25]. In addition, the PPV was only 0.32, which may not be sufficient for routine clinical use. Meanwhile, the PPV of the cutoff point 7/8 exceeded 0.5. Although the cutoff point 7/8 would miss 2.4%

Table 3
SSLRs of the PHQ-9 dimensional assessment

Stratum	0–4	5–9	10 and over
SSLR	0.16 (95% CI: 0.07–0.33)	2.54 (95% CI: 1.54–4.20)	23.05 (95% CI: 12.51–42.47)

Posterior probability is greater than the prior probability if the SSLR is >1.0. The former is smaller than the latter if the SSLR is <0.1. An SSLR >10 makes the target disorder highly probable, whereas one smaller than 0.1 usually rules it out. SSLRs between 10 and 5 or between 0.1 and 0.2 are often very informative, while those between 0.5 and 2 would be of little assistance in the diagnosis [40].



Validity of the Patient Health Questionnaire (PHQ)-9 and PHQ-2 in general internal medicine primary care at a Japanese rural hospital: a cross-sectional study^{☆,☆☆,★}

Masatoshi Inagaki, M.D., Ph.D.^{a,b,*}, Tsuyuka Ohtsuki, Ph.D.^b, Naohiro Yonemoto, Ph.D.^c, Yoshitaka Kawashima, Ph.D.^d, Akiyoshi Saitoh, Ph.D.^d, Yuetsu Oikawa, M.D.^e, Mie Kurosawa, M.D., Ph.D.^f, Kumiko Muramatsu, M.D., Ph.D.^g, Toshi A. Furukawa, M.D., Ph.D.^{h,i}, Mitsuhiro Yamada, M.D., Ph.D.^d

^a Department of Neuropsychiatry, Okayama University Hospital, Okayama, Japan

^b Center for Suicide Prevention, National Institute of Mental Health, National Center of Neurology and Psychiatry, Tokyo, Japan

^c Translational Medical Center, National Center of Neurology and Psychiatry, Tokyo, Japan

^d Department of Neuropsychopharmacology, National Institute of Mental Health, National Center of Neurology and Psychiatry, Tokyo, Japan

^e Oshu City Magokoro Hospital, Iwate, Japan

^f Iwate Mental Health Center, Iwate, Japan

^g Clinical Psychology Course, Graduate School of Niigata Seiryō University, Niigata, Japan

^h Department of Health Promotion and Human Behavior, Kyoto University Graduate School of Medicine / School of Public Health, Kyoto, Japan

ⁱ Department of Clinical Epidemiology, Kyoto University Graduate School of Medicine / School of Public Health, Kyoto, Japan

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ABSTRACT

Objective: Two depression screening tools, Patient Health Questionnaire (PHQ)-9 and PHQ-2, have not had their validity examined in general internal medicine settings in Japan. We examined the validity of these screening tools.

Methods: A total of 598 outpatients of an internal medicine clinic in a rural general hospital were enrolled consecutively and stratified by PHQ-9 score. Seventy-five patients randomly selected and 29 patients whose results from the PHQ-9 were considered to be positive for depressive disorder were then interviewed with a semistructured interview, the Mini International Neuropsychiatric Interview. We calculated diagnostic accuracy of the PHQ-9 and PHQ-2 to detect major depression and that of the suicidality item of the PHQ-9 to detect suicidality using sampling weights with multiple imputations.

Results: Sensitivity and specificity for depression were 0.86 and 0.85, respectively, for the PHQ-9 with cutoff points of 4/5, and 0.77 and 0.95, respectively, for the PHQ-2 with cutoff points of 2/3. Sensitivity and specificity of the suicidality item of the PHQ-9 were 0.70 and 0.97, respectively.

Conclusion: In internal medicine clinics in Japanese rural hospitals, the PHQ-2 with an optimal cutoff point for each setting plus the suicidality item of the PHQ-9 can be recommended to detect depression without missing suicidality.

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1. Background

Depression is prevalent [1–4], and its influence on quality of life is profound. In middle-income and high-income countries including Japan, depression was the leading cause of disability in 2004 [5]. Prevalence of depression is reported to be high in health care settings [6–8]. The World Health Organization performed a primary care mental health survey across 14 countries and found that 14% of primary care patients suffered from major depression [7]. However, a meta-analysis showed that many depressed patients were overlooked and that many nondepressed patients were misdiagnosed as having depression [9]. Thus, development of a valid screening tool is required in health care settings.

The Patient Health Questionnaire (PHQ)-9 is one of the commonly used validated screening tools for depression in various settings including primary care and general practice [10–14]. The PHQ-9 has

two different assessment methods. One uses a categorical (yes/no) algorithm to screen for depression. In the categorical algorithm, the depression screening is positive if five or more of the nine depressive symptom criteria are endorsed and one of the symptoms is anhedonia or depressed mood. The other is a dimensional (continuous scale) assessment. In the dimensional assessment, the sum of the PHQ-9 scores is calculated, and an a priori cutoff score is applied. Using the categorical algorithm, the sensitivity and specificity shown in a meta-analysis were 0.77 [95% confidence interval (CI): 0.71–0.84] and 0.94 (95% CI: 0.90–0.97), respectively [14]. In comparison, the sensitivity and specificity of the dimensional assessment using cutoff scores for the PHQ-9 in primary care settings that were calculated in another meta-analysis were 0.86 (95% CI: 0.66–0.97) and 0.88 (95% CI: 0.80–0.93), respectively [12]. A third meta-analysis showed the sensitivity and specificity of the dimensional assessment using the cutoff score 9/10 as 0.81 (95% CI: 0.72–0.88) and 0.92 (95% CI: 0.83–0.97), respectively [10]. However, these studies showed major variability in the optimal cutoff point [10,12]. A cutoff point of around 10 was recommended in a previous publication [15] and shown to be the optimal cutoff point in a previous study using meta-analysis [12]. However, the optimal cutoff point score has been reported as lower in elderly populations [16,17], a population in Korea [16] and a community sample in rural Pakistan [18]. In addition, the sensitivity using this cutoff point was relatively low (sensitivity: 0.50–0.69) [19–21] in some settings including a hospital setting [22,23] and a family practice clinic (sensitivity: 0.53) [24].

In Japan, especially in rural areas, most patients consult a general internist who plays a role similar to that of a primary care physician or a general practitioner. We reported the prevalence of depression in an internal medicine outpatient clinic in a rural general hospital as 7.4% [25]. In that study, we showed that a critical symptom, suicidality, was present in 12.7% [25]. In a previous study, however, we also reported that physicians overlooked many symptoms of depression and did not pay attention to diagnosing depression [26]. Thus, a screening tool to support depression identification has to be developed and used widely. However, there is no screening tool for which the validity has been confirmed in such primary care settings in Japan.

Therefore, in the present study, we examined the validity of the Japanese versions of the PHQ-9 and PHQ-2 in an internal medicine outpatient clinic in a rural general hospital, which has a role in the primary care of the residents in the area. In addition, we examined the validity of the suicidality item of the PHQ-9 to detect suicide ideation as ascertained by a semistructured interview because the PHQ-2 does not include the question of suicidality and may cause the clinician to miss this critical symptom.

2. Methods

2.1. Participants

The sampling process and procedures of the study have been reported previously [25] and are described briefly below. This study was conducted on 9 consecutive consultation days between July 12 and 23, 2010, at an internal medicine outpatient clinic in a general hospital having no mental health specialties. This hospital is located in a small city (population of 124,756 in 2010) in the Tohoku region of Japan. The hospital serves as a regional public hospital and is funded by the National Health Insurance Society in Oshu. The city is located in a typical rural area about 500 km north of Tokyo with low population influx. There are high proportions of elderly people and people engaged in primary industry [27].

We used the following inclusion criteria to define a target population to be assessed for depression: (1) patients aged 20 or older who visited the outpatient clinic to consult a physician for their own primary care and (2) patients who have no communication difficulties, such as hearing loss or language problems, and who have

no severe cognitive impairment, such as dementia or disturbance of consciousness. Thus, we did not include visitors who came in for admission preparation or those who consulted for their family members. We did not include patients who lived outside the catchment area of the hospital. Severe cognitive impairment was judged based on a semistructured interview using the first two questions of the Mini-Mental State Examination concerning time and place orientation [28,29]. This was administered by research staff consisting of two psychiatrists (M.I. and M.Y.), a research assistant (T.O.) having experience in surveys using the Mini-Mental State Examination and PHQ-9 in internal medical clinics, and nurses. The staff sometimes conducted an additional interview about patients' lifestyle factors and dementia history if accompanying persons were present. For ethical reasons and for the feasibility of the survey, we also excluded patients who were too physically ill to be interviewed.

This study was approved by the ethics committee of the National Center of Neurology and Psychiatry in Japan. The researchers provided all participants with detailed information using a written document and administered a battery of self-report questionnaires (PHQ-9) [15,30] after the patients provided oral informed consent. After this first-stage screening to stratify the participants, we conducted the structured psychiatric interviews [Mini International Neuropsychiatric Interview (MINI)] [31,32] with patients who provided further written informed consent.

2.2. Measurements

2.2.1. PHQ-9

The PHQ-9 is a widely used screening tool in health care settings [15,30]. The PHQ-9 is a self-report questionnaire consisting of nine questions asking about depression symptoms such as anhedonia, depressed mood and suicidality. The PHQ-9 was translated into Japanese (the Japanese version of PHQ-9) through back translation and validated in a previous study [30]. We asked patients to choose from the following options how often they had been bothered by each of the nine symptoms over the last 2 weeks: "Not at all," "Several days," "More than half the days" and "Nearly every day."

A categorical algorithm has been proposed in the literature [15,30] to assess the PHQ-9 results. In the categorical algorithm, the depression screening is positive if five or more of the nine depressive symptom criteria are endorsed as having been present at least "more than half the days" and one of the symptoms was anhedonia or depressed mood. One of the nine items, "thoughts that you would be better off dead or of hurting yourself in some way," is counted if present at all. In addition to the categorical algorithm of the PHQ-9, we adopted a two-item categorical algorithm with the first two items of the PHQ-9 (anhedonia and depressed mood). In the two-item categorical algorithm, depression screening is positive if one or more of the two depressive symptom criteria are endorsed as having been present.

Alternatively, we calculated the sum of the PHQ-9 scores as a dimensional assessment of the PHQ-9. Each item of the PHQ-9 is scored from 0 to 3, with a total possible score of 27 for the nine items. Also, we calculated the sum of the PHQ-2. A total possible score of the PHQ-2 was 6.

2.2.2. MINI

We diagnosed major depressive episode using the Major Depressive Episode module of the MINI [31,32]. The interview was originally developed as a semistructured diagnostic interview compatible with the *Diagnostic and Statistical Manual of Mental Disorders, Revised Third Edition*, (DSM-III-R) and *International Classification of Diseases, 10th Revision*, criteria [33,34]. The MINI was translated in a previous study [31] through the standard procedure of back translation for the cross-cultural adaptation of an original English psychometric instrument [35]. The Japanese version of the MINI was validated using the

Table 4
Generalized linear regression models stratified by CVD conditions examining associations of comorbid psychological distress and out-of-pocket burdens

CVD conditions and psychological distress	OOP burdens, M	Crude burden ratio ^a (95% CI)	Adjusted burden ratio ^b (95% CI)
With diabetes			
SPD	11.3	1.74 (0.86–3.15)	1.76 (0.98–2.95)
MPD	4.8	1.11 (0.66–1.78)	1.20 (0.79–1.78)
Noncase	6.4	1	1
Without diabetes			
SPD	3.6	1.97 (1.66–2.33)*	2.08 (1.77–2.43)*
MPD	2.5	1.41 (1.23–1.62)*	1.42 (1.25–1.62)*
Noncase	1.7	1	1
With obesity			
SPD	14.1	5.70 (2.09–14.67)*	6.07 (2.14–16.63)*
MPD	4.1	0.45 (0.06–1.78)	2.09 (0.35–8.44)
Noncase	5.0	1	1
Without obesity			
SPD	3.7	1.91 (1.61–2.25)*	2.02 (1.72–2.35)*
MPD	2.6	1.42 (1.24–1.62)*	1.42 (1.25–1.61)*
Noncase	1.8	1	1
With hyperlipidemia			
SPD	10.5	2.82 (1.39–5.16)*	1.53 (0.84–2.67)
MPD	7.1	1.24 (0.62–2.26)	1.28 (0.74–2.11)
Noncase	6.4	1	1
Without hyperlipidemia			
SPD	3.6	1.91 (1.60–2.25)*	2.03 (1.73–2.37)*
MPD	2.5	1.42 (1.24–1.63)*	1.41 (1.24–1.60)*
Noncase	1.7	1	1
With hypertension			
SPD	10.3	3.44 (2.02–5.51)*	2.56 (1.58–4.00)*
MPD	6.0	1.24 (0.74–1.97)	1.09 (0.70–1.63)
Noncase	5.6	1	1
Without hypertension			
SPD	3.5	1.91 (1.60–2.27)*	1.93 (1.63–2.26)*
MPD	2.4	1.46 (1.27–1.68)*	1.39 (1.21–1.58)*
Noncase	1.7	1	1
With stroke			
SPD	17.2	2.54 (0.76–6.92)	2.95 (0.86–9.04)
MPD	5.1	0.57 (0.11–1.86)	0.57 (0.12–1.87)
Noncase	7.4	1	1
Without stroke			
SPD	3.6	1.92 (1.62–2.26)*	2.03 (1.73–2.37)*
MPD	2.5	1.42 (1.24–1.62)*	1.41 (1.25–1.60)*
Noncase	1.8	1	1
With ischemic heart disease			
SPD	11.1	0.96 (0.20–2.86)	3.43 (1.29–8.53)*
MPD	6.6	0.49 (0.08–1.57)	1.38 (0.51–3.19)
Noncase	9.5	1	1
Without ischemic heart disease			
SPD	3.7	1.98 (1.67–2.31)*	2.07 (1.77–2.41)*
MPD	2.5	1.44 (1.26–1.64)*	1.44 (1.26–1.63)*
Noncase	1.8	1	1
With other cardiovascular			
SPD	13.3	2.19 (0.65–5.69)	2.11 (0.75–5.30)
MPD	4.7	0.73 (0.24–1.79)	0.89 (0.37–1.91)
Noncase	7.7	1	1
Without other cardiovascular			
SPD	3.7	1.95 (1.64–2.29)*	2.05 (1.75–2.39)*
MPD	2.5	1.42 (1.23–1.62)*	1.42 (1.25–1.60)*
Noncase	1.8	1	1

OOP Burdens, out-of-pocket health care expenditures as a share of household consumption expenditures.

^a The reference groups were defined as a score on the K6 of 0–8.

^b Burden ratios after simultaneously controlling for potential confounders that were gender, age, marital status, employment status, pension status, urbanicity, and number of cardiovascular risks and events.

* $P < .05$.

comorbid SPD may increase the severity of CVD conditions (or vice versa), which would in turn increase direct medical costs. For example, patients with heart failure and depression had 29% greater direct medical costs than those with only heart failure because of

increased utilization of inpatient and outpatient treatments [6]. Second, the presence of SPD may lead to loss of income due to absence from work. A large cross-sectional study revealed that patients with chronic illness and depression were more likely to be absent from work than those with only chronic illness in the Canadian general population [7]. Our results suggest that CVD patients comorbid with SPD face a dual economic burden, namely, excess direct medical costs and income loss. To measure individual out-of-pocket burdens, we focused on the general population who lived alone, and thus, they could not share financial resources of their family members to overcome their out-of-pocket burdens. Policymakers need to find solutions to reduce the high out-of-pocket burdens for CVD patients comorbid with SPD. Such solutions may be preferable and effective for patients comorbid with SPD rather than MPD, out-of-pocket burdens of which are similar to the burdens of patients with only CVD conditions.

Our results may be conservative estimates of out-of-pocket burdens among Organization for Economic Co-operation and Development (OECD) countries. In general, the average out-of-pocket burden in Japan (2.2%) is 70% lower than the OECD average (3.1%) [16] because Japan's universal health care system has led to excellent public health at low costs with equity [17]. Therefore, CVD patients comorbid with SPD would face more out-of-pocket burdens in other countries.

Our study had several limitations. First, there was a possibility for false-positive and false-negative results because the status of psychological distress was based on self-rated data using the K6 scale. A previous validation study [27] showed that the positive predictive value for the K6 scores of 14–24 is 85% in a population with a 5% prevalence of any *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition*, mood or anxiety disorder at present (e.g., patients with CVD conditions). Based on a validation study [27] and the hypothetical prevalence of 5%, 15% of defined CVD patients comorbid with SPD would not meet current diagnoses for any mood or anxiety disorder. Second, CVD condition status was also based on a self-report checklist that noted whether they were currently being treated for any condition for CVD conditions in a noninstitutionalized setting. Therefore, current findings may not be generalized to either untreated or institutionalized individuals with CVD conditions. Third, the generalizability of the present study was also limited to 20- to 59-year-old individuals living alone. In addition, we cannot rule out the possibility of selection bias caused by including only individuals living alone because living status might be associated with both psychological distress and CVD conditions. Finally, the present study had limitations inherent to cross-sectional studies that cannot establish causality of associations.

In conclusion, our findings indicate that individuals with CVD conditions may have SPD and that this comorbidity was associated with high out-of-pocket burdens in a representative sample of Japanese individuals living alone. The present study suggests that physicians should identify and manage SPD in patients with CVD conditions and that policymakers should find solutions to reduce the high out-of-pocket burdens among these patients.

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Prevalence of depression among outpatients visiting a general internal medicine polyclinic in rural Japan ☆, ☆ ☆

Masatoshi Inagaki, M.D., Ph.D.^{a, b, *}, Tsuyuka Ohtsuki, Ph.D.^a, Naohiro Yonemoto, Ph.D.^c, Yuetsu Oikawa, M.D.^d, Mie Kurosawa, M.D., Ph.D.^e, Kumiko Muramatsu, M.D., Ph.D.^f, Toshi A. Furukawa, M.D., Ph.D.^g, Mitsuhiro Yamada, M.D., Ph.D.^b

^a Center for Suicide Prevention, National Institute of Mental Health, National Center of Neurology and Psychiatry, Kodaira City, Tokyo, Japan

^b Department of Psychopharmacology, National Institute of Mental Health, National Center of Neurology and Psychiatry, Kodaira City, Tokyo, Japan

^c Translational Medical Center, National Center of Neurology and Psychiatry, Kodaira City, Tokyo, Japan

^d Oshu City Magokoro Hospital, Oshu City, Iwate, Japan

^e Iwate Mental Health Center, Morioka City, Iwate, Japan

^f Clinical Psychology Course, Graduate School of Niigata Seiryō University, Niigata City, Niigata, Japan

^g Department of Health Promotion and Human Behavior, Kyoto University, Kyoto City, Kyoto, Japan

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ABSTRACT

Objective: In Europe and the US, primary care has been anticipated in identifying untreated depression. Findings show a high prevalence of depression in such settings. However, the prevalence of depression in an internal medicine clinic in a rural area of Japan, which has a role in primary care, is unclear.

Method: The prevalence of depression and comorbid psychiatric disorders among outpatients of an internal medicine clinic in a rural general hospital was measured by a structured interview using the Mini International Neuropsychiatric Interview. Outpatients were recruited consecutively and stratified by Patient Health Questionnaire-9 (PHQ-9) scores. Among 598 outpatients, we interviewed 75 randomly selected patients and 29 whose results of the PHQ-9 were positive. We estimated prevalence of depressive episode using age, sex, physical findings by internal medical doctors and PHQ-9 scores as covariates.

Results: The estimated prevalence of major and minor depressive episodes were 7.4% [95% confidence interval (CI): 3.4%–11.4%] and 6.8% (95% CI: 2.6%–10.9%), respectively. Among major depressed patients, 71.4% had current suicidal ideation.

Conclusion: Given the high rate of depression and suicidality, identification of depression and collaboration between internal medical doctors in a rural area of Japan and mental health professionals are needed.

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1. Background

Depression is a prevalent, disabling disorder that has a profound influence on quality of life. It is estimated to become the leading cause

of disability worldwide in 2030 and was already the leading cause of morbidity in middle- and high-income countries, including Japan, in 2004 [1].

Previous studies have invariably reported a high prevalence of depression in the general population [2–5] and in health care settings [6–8]. For example, the World Health Organization (WHO) performed a primary care mental health survey of 14 countries and found that 14% of primary care patients suffered from major depression [6]. Given the high prevalence of depression, primary care settings play an important role in identifying and treating depressed patients [9–11]. In Japan, there are few doctors specialized to primary care because its medical system has no clear definition of primary care and the specific providers responsible. Most patients, especially those in rural areas, consult an internal medical doctor for their primary care.

A previous study of patients in a general medicine clinic showed a 4.7% lifetime prevalence of major depressive episodes [12]. Another survey, also performed about 20 years ago, showed a 3.0% prevalence

of major depressive episodes [13]. However, there are few recent studies showing depression prevalence in primary care settings.

Recently, we reported the prevalence of depression in a rural general hospital, where many of the patients were elderly [mean age (S.D.)=72.9 (12.5) years]. Approximately 53%, 12% and 10% of the patients suffered from hypertension, hyperlipidemia and diabetes, respectively, which suggested that this rural general hospital played a role in the primary care of chronic physical illnesses of elderly patients [14]. Using the Patient Health Questionnaire-9 (PHQ-9), 8.7% [95% confidence interval (CI), 5.5%–11.8%] presented with probable major depression and, 16.7% (12.5%–20.8%), with a probable mood disorder. However, these prevalence estimates were based only on self-reports, and we did not perform any structured interviews to diagnose depression. There were also no data regarding comorbid psychiatric disorders that are commonly observed in primary care settings [15,16]. Therefore, the present study used structured psychiatric interviews to elucidate the prevalence of depression and other psychiatric disorders among patients of a general internal medicine outpatient clinic in a rural area of Japan.

2. Methods

2.1. Participants

This study was approved by the Ethics Committee of the National Center of Neurology and Psychiatry in Japan. The researchers provided all participants with detailed information using a written document and administered a battery of self-report questionnaires after the patients provided oral informed consent. After this first-stage screening, we conducted structured psychiatric interviews with patients who provided further written informed consent.

This study was conducted on nine consecutive consultation days between July 12 and 23, 2010, at a general internal medicine outpatient clinic in a general hospital having no mental health specialties. This hospital is located in a small city (population of 124,756 in 2010) in the Tohoku region of Japan. The hospital serves as a regional public hospital and is funded by the National Health Insurance Society of Oshu City. Oshu City is a typical rural area about 500 km north of Tokyo with low population influx. There are high proportions of elderly people and people engaged in primary industry [17].

We used the following inclusion criteria to define a target population that can be assessed for depression in routine clinical practice: (a) patients aged 20 years or older who visited the outpatient clinic to consult a physician for their own primary care and (b) patients who have no communication difficulties, such as hearing loss or language problems, and who have no severe cognitive impairment, such as dementia or disturbance of consciousness. Thus, we did not include visitors who came in for admission preparation or those who consulted for their family members. We also did not include patients who lived outside the catchment area of the hospital. Severe cognitive impairment was judged based on a semistructured interview, using the first two questions of the Mini-Mental State Examination concerning time and place orientation [18,19] by research staff consisted of psychiatrists (MI and MY), a research assistant (TO) having experience in survey using the Mini-Mental State Examination and PHQ-9 in internal medical clinics and nurses. All were trained for the procedure of the present study. The staff sometimes conducted an additional interview regarding patient lifestyle factors and dementia history if accompanying persons were present. Due to ethical considerations and feasibility of the survey, we also excluded patients who were too physically ill to be interviewed.

2.2. Measurements

2.2.1. PHQ-9

We used the PHQ-9 [20,21] to stratify participants. We asked patients to choose from the following options how often they had

been bothered by each of nine symptoms over the last 2 weeks: “not at all,” “several days,” “more than half the days” and “nearly every day.” Two scoring methods, a categorical algorithm and a dimensional assessment, have been proposed in the literature. In the categorical algorithm, depression screening is positive if five or more of the nine depressive symptom criteria were present at least more than half the days and one of the symptoms is depressed mood or anhedonia. One of the nine items, “thoughts that you would be better off dead or of hurting yourself in some way,” was counted if present at all. In addition to the categorical algorithm, we judged depression severity using a dimensional scale, with a cutoff score of 10 reported as optimal for screening probable depression. Each item is scored from 0 to 3, with a total possible score of 27 for the nine items.

We used a categorical algorithm to screen probable depression positive. In the categorical algorithm, depression is positive if one of two items (depressed mood or anhedonia) was present. Based on the results of the PHQ-9, patients were screened as probable depression positive using either the categorical algorithm (one of the two items) or the dimensional assessment (score of more than 10).

2.2.2. Mini International Neuropsychiatric Interview (MINI)

We used the MINI [22,23] to diagnose depression and other psychiatric disorders. The interview was originally developed as a structured diagnostic interview compatible with DSM-III-R and ICD-10 criteria [25,26]. The MINI focuses on current diagnoses and only explores lifetime diagnoses clinically if relevant to the present status. For most diagnostic sections, one or two screening questions are used to rule out the diagnosis when answered in the negative. The MINI includes 19 disorders chosen as most common from epidemiological data [27,28]. In the present study, we used the modules related to depression, anxiety, eating disorders and alcohol/substance dependence/abuse, which are often observed in primary care settings [16]. We evaluated current suicidality using the suicidality module (C) of the MINI, although the validity has not been completely established [22–24]. The module consists of six items that identify any suicide-related episodes or phenomena, including suicidal ideation within the last month (five items) and history of suicide attempts (one item) in the life. If any items in the suicidal ideation within the last month (five items) were relevant, we judged that current suicidality was present. In addition, we calculated the score (e.g., lifetime histories of attempting suicide=4, presence of having suicidal ideation within a month=6, planning or attempting suicide within a month=10) and showed the number of patients with a high risk (MINI suicide risk >= 10) as severe suicidality [22–24]. In addition to the current suicidality evaluated by the MINI, we investigated score of the Item 9 in the PHQ-9 (thoughts that you would be better off dead or of hurting yourself in some way; *not at all*: 0; *several days*: 1; *more than half the days*: 2; and *nearly every day*: 3, over the past 2 weeks). We confirmed that scores of the Item 9 among patients with current suicidality by the MINI (median: 1; range: 0–3) were significantly higher than those among patients without (median: 0; range: 0–1) ($U=273.5$, $P<.01$ by the Mann-Whitney U test). We also used the MINI to assess minor depressive episodes, defined as having two to four items, with one of the items being depressed mood or anhedonia in the major depressive episode module (A) of the MINI.

2.3. Procedure

We defined the target population by the inclusion criteria described in the participant section and adopted a random sampling stratified by the PHQ-9 results. Trained psychiatrists (MI or MY), who were blind to the results of the PHQ-9, conducted structured MINI interviews of patients who were screened as probable depression positive as well as randomly selected patients.

2.3.1. Statistical analyses

We calculated the prevalence estimates of any depressive episode (major depressive episode and minor depressive episode), other psychiatric disorders and their 95% CIs using sampling weights. The weight was based on the inverse of the sampling probability for age, sex, clinical diagnosis of primary illness and PHQ-9 score. We performed multiple imputations for the missing data. We performed all statistical analyses using the statistical software packages SPSS 17.0 (IBM, Tokyo) and Statistical Analysis System (SAS) 9.2 (SAS Institute Japan, Tokyo).

3. Results

During the study period, 598 patients visited the clinic. We randomly selected 107 of the outpatients. From the selected 107 patients, we excluded 21 based on our inclusion criteria: 1 was less than 20 years old, 7 consulted for family members, 1 resided outside the area and 12 were severely cognitively impaired. Among the 86 patients, 5 patients were physically too ill, and 1 refused to participate in the study. Then we administered the PHQ-9 to 80 patients who agreed to participate in the survey.

Among the remaining 491 patients who were not selected randomly, we excluded 66 based on our inclusion criteria: 16 were less than 20 years old, 15 consulted for family members, 1 visited to prepare for admission, 2 resided outside the area and 32 were severely cognitively impaired. Among the 425 patients, 12 were physically too ill, 4 were missed and 5 refused to participate in the study. Then, we administered the PHQ-9 to 404 patients and acquired PHQ-9 data for 396 of the 404 patients, and 8 of PHQ-9 data were incomplete. As a result, 36 patients out of the 396 were screened as probable depression positive.

Among the total 116 participants (80 and 36 participants), 104 received a structured interview using the MINI. Twelve patients were not interviewed (seven were missed, one was physically ill and four refused the interview).

The target population to estimate prevalence was 511 patients (86 and 425 patients).

Table 1 shows characteristics of the target population ($n=511$). The median age of the population was 75 years, with more than 81.8% of participants being 65 years old or older. As shown in Table 1, chronic physical illnesses, such as hypertension, diabetes and hyperlipidemia, were frequent. The median number of visits in the past 6 months was four, which means many patients consulted the clinic approximately once every 6 weeks.

Of the 104 patients who we interviewed using the MINI, we diagnosed 21 as having experienced a major depressive episode and 15 with a minor depressive episode. One had a hypomanic episode, two had posttraumatic stress disorder (PTSD) and five had alcohol dependence. Twenty-seven patients had suicidal thoughts. No one had a high risk of suicide among 99 patients who completed the suicidality module of the MINI (five had incomplete data). Table 2 shows weighted prevalences of depression and other psychiatric disorders. The estimated prevalence of having a major depressive

Table 1
Characteristics of the study participants

Characteristic	Number	% (21–102)
Median age (range) in years	75	(21–102)
Sex: female (%)	59.3	
Clinical diagnosis of primary illness (%)		
Hypertension	58.7	
Diabetes	16.0	
Hyperlipidemia	15.9	
Brain infarction	8.4	
Arrhythmia	6.8	
Number of visits in the past 6 months		
Median (range)	4	(0–74)

Table 2
Prevalence of depression and other psychiatric disorders

Disorder	Estimated prevalence (%)	(95% CI)
Any depressive episode	14.1	8.2–20.0
Major depressive episode (current, 2 weeks)	7.4	3.4–11.4
Minor depressive episode (current, 2 weeks)	6.8	2.6–10.9
Hypomanic episode (current)	0.8	0.0–2.4
PTSD (current, past month)	1.4	0.0–3.4
Alcohol dependence (past 12 months)	5.4	0.3–10.5
Current suicidality	12.7	6.6–18.9

episode was 7.4% (95% CI: 3.4% to 11.4%). That of any depressive episode, including both major and minor depressive episode, was 14.1% (95% CI: 8.2% to 20.0%), which means that one in every seven patients was estimated to have depression. Prevalence of current suicidality was 12.7% or one in every eight patients. Alcohol dependence was also frequent (5.4%).

Table 3 shows the prevalence of comorbid psychiatric disorders and current suicidality among patients that experienced a depressive episode. Prevalence of suicidality was high in patients with a major depressive episode as well as those with any depressive episode. Among the patients with major depressive episode ($n=21$), median (range) of the scores of Item 9 of the PHQ-9 was 1 (0–3). Among those diagnosed as having any depressive episode ($n=36$), median (range) of the scores was 0 (0–3). And among those who had no depressive episode, median (range) of the scores was 0 (0–1). Proportions of patients who scored the Item 9 of the PHQ-9 as 3 (nearly every day over the past 2 weeks) were 38.1%, 22.2% and 0% among patients with major depressive episode ($n=21$), those with any depressive episode ($n=36$) and those without any depressive episode ($n=68$), respectively.

4. Discussion

The present study investigated the prevalence of depression and other psychiatric disorders in a general internal medicine outpatient clinic of a Japanese rural general hospital using structured interview conducted by trained psychiatrists followed by screening of PHQ-9. Patients were elderly and had chronic physical illnesses. The prevalence of major depressive disorder was 7.4% and, that of depression including both major and minor depressive disorders, was 14.1%. The prevalence of alcohol dependence was high, and suicidality was prevalent among patients with major or minor depressive disorders.

A previous survey conducted by the WHO nearly 20 years ago reported the prevalence of depression as 3.0% in internal medicine outpatient clinics in Japan [13]. The prevalence of PTSD in the previous survey (0.2%) was also lower than that of the present study (1.4%). The prevalence of alcohol dependence in the previous survey was 6.2%, which was comparable to that of the present study (5.4%). In contrast, the prevalence of generalized anxiety disorder was 5.0% in

Table 3
Rate of comorbid psychiatric disorders in patients with depression

Disorder	Number	%
Major depressive episode ($n=21$)		
Current suicidality	15	71.4
PTSD	1	4.8
Alcohol dependence	0	0
Any depressive episode ($n=36$)		
Current suicidality	18	50.0
PTSD	2	5.6
Alcohol dependence	1	2.8

the previous survey, while no patients had generalized anxiety disorders in the present study.

These discrepancies may be explained by differences in participants and methods between the previous survey and the present study. The previous survey was conducted in a hospital located in a medium-sized city, whereas we examined prevalence of psychiatric disorders in a rural hospital. The previous survey excluded patients older than 65 years old, while the majority of participants in the present study were older than 65 years old. In addition, we need to consider that the previous survey was performed nearly 20 years ago.

A previous study performed in the US showed that the prevalence of major depression in rural primary care (8.3%) was lower than that in urban primary care settings (14.8%) [29]. The internal medicine clinic in the present study was located in a rural area, and the prevalence of major depression (7.4%) was similar to that previously reported [29]. However, the prevalence of depression in an urban clinic in Japan may be different.

Our previous study using the PHQ-9 to identify probable depression in the same clinic showed that prevalence of probable major depressive disorders (8.7%, 95% CI: 5.5%–11.8%) [14] was similar to that of the present study, suggesting that the results are reproducible.

The present study showed a high prevalence of current suicidality. In addition to the high prevalence, there was a higher rate of current suicidality among patients with major depressive episodes. Thus, current suicidality should be considered in addition to depression in patients evaluated at internal medicine clinics of rural general hospitals. In particular, referral of depressed patients with suicidal thought more than several days in the past 2 weeks to mental health professionals is required.

Previous studies in other countries showed that the prevalence of major depression in primary care settings for people aged 65 or older is 19.5% [30], which is higher than the prevalence found in the present study. The prevalence of depression in the general Japanese population is 2.9% [31], which is lower than that in other countries [32]. The lower prevalence in the general population may reflect the lower prevalence of depression in general internal medicine outpatient clinics.

The prevalence of depression in the internal medical outpatient clinic shown in the present study was higher than that previously reported for the general population in Japan [31]. This is similar to findings from other countries where the prevalence of depression in primary care settings is higher than in the community [30,33]. These results suggest that depressed patients more frequently consult internists. Thus, it is important that physicians appropriately identify, treat and/or refer untreated depressed patients that consult the clinic to mental health specialists.

The study has two major limitations. First, we selected only a single hospital for convenience. A survey of multiple, randomly selected sites from across Japan should be performed to generalize the findings. Second, the number of participants in the study was too small to effectively investigate comorbidities.

The present study showed a high prevalence of depression in an internal medicine outpatient clinic of a rural general hospital that plays a role in primary care for residents of its catchment area. We also showed a high prevalence of suicidality and its higher comorbidity rate with depression. Given the high rate of depression and suicidality, identification of depression and collaboration between internal medical doctors and mental health professionals, such as psychiatrists, are needed.

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うつ病の発見と治療に必要な、 かかりつけ病院と院外資源との連携のために

稲垣 正俊^{1,2)*}、大槻 露華¹⁾、長 健³⁾、山田 光彦⁴⁾

抄録：

わが国では、うつ病相当にもかかわらず、適切な支援を受けていない患者が多く存在する。一部は、一般身体科診療科を受診しているが、そこでもうつ病と診断されず、結果として適切な治療に導入されていない患者が多い。そこで、かかりつけ病院においてうつ病を発見し、適切な治療へと導入するモデルを検討するとともに、その際に必要な、かかりつけ病院とかかりつけ病院の外の様々な支援サービスとの連携準備について検討した。

わが国のうつ病有病率、かかりつけ病院医師のうつ病認識率、かかりつけ病院におけるうつ病スクリーニング性能、精神科医以外の医師のうつ病治療の考え方、および、海外のプライマリ・ケア場面におけるうつ病診療体制等の根拠に基づき、モデル案を検討した。

その結果、看護師中心の多職種協働ステップ治療モデルとして、定期的な全患者へのうつ病スクリーニングの実施と、うつ病スクリーニングにおいて陽性と判断された患者に対する看護師中心のケースマネジメントの実施、病院外の資源による支援、必要に応じて病院外の資源への紹介というモデルが検討された。また、このモデルの実施に際しては、院内の医療従事者の教育やロジスティックといった準備だけでなく院外の様々なサービスや団体との事前の連携構築が必要であることが認識された。

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索引用語：うつ病, 多職種協働ケア, かかりつけ医, スクリーニング, ケースマネジメント
Depression, Collaborative care, Primary care, Screening, Case management

はじめに

近年、うつ病により病院等を受診する患者が増加している。うつ病を患う個人の苦痛は非常に大きく、時に自殺という破局的な結果を招く。家族の負担も大きく、社会的な影響を含め、その負担は非常に大きい。

わが国では、年間の自殺者数が3万人を超える状態が10年以上続いた中で、国としての自殺総合対策を示した自殺総合対策大綱が閣議決定された。その中に「うつ病の早期発見・早期治療」のために「自殺の危険性の高い人を発見する機会の多いかかりつけの医師等をゲートキーパーとして養成し、うつ病対策に活用するとともに、精神科

医療提供体制の整備を図る必要がある。」と記述されている。

海外のプライマリ・ケア医療場面における うつ病の発見と治療導入

海外のプライマリ・ケアや一般診療科の診療場面では、うつ病患者が多いことが研究で示されている。Spitzerらの調査では¹⁴⁾、プライマリ・ケア場面において、何らかの精神科診断のついた患者が39%で、大区分では何らかの気分障害が26%と多く、その気分障害の中では、大うつ病性障害が12%と多いという結果であった。他の研究者からも同様の結果が示されており、プライマリ・ケア場面におけるうつ病への対応の重要性が認識されている。

有病率の高いうつ病ではあるが、プライマリ・ケア医はうつ病に気づいていないということも同時に指摘されており、うつ病患者を見逃さずに同定するために、うつ病スクリーニングを実施し、必要な患者を適切な治療へと導入することが重要だとされている。実際、プライマリ・ケア場面において妥当性が確認されたうつ病スクリーニングが開発されている^{7,13)}。また、うつ病スクリーニングを実施した場合としない場合で医師がどの程度うつ病に気づくか、といった研究結果をメタ解析により分析した研究では、うつ病スクリーニングを実施することで、うつ病に気づきやすくなる、という結果が示されている⁶⁾。

うつ病スクリーニングだけでなく、スクリーニング陽性となった患者の診断やその後の適切な治

療を実施できる枠組みを作る重要性も強調されている。実際、うつ病スクリーニングで陽性となった患者に対して適切な治療を導入するための体制を構築せずにうつ病スクリーニングを実施しても、効果がないことも示されている²⁾。

プライマリ・ケア場面において有効なうつ病治療の体制としては、Collaborative Stepped Care (多職種協働ステップ治療)が示されており、無作為化比較試験だけでなく、メタ解析によってもその効果が示されている²⁾。この多職種協働ステップ治療には、様々な介入要素が混在して実施されているが、メタ回帰分析手法を用いた研究からは、「精神保健の教育を受けたケースマネージャーの配置」、「定期的な精神保健の専門家によるスーパービジョン」、「系統的なうつ病スクリーニングの実施」が効果と関連する要素だと示されている¹⁾。また、この多職種協働ステップ治療では、軽症から中等症の患者をプライマリ・ケア場面でもケースマネジメントしながら治療を実施するが、中等症から重症の患者等の、より専門の精神科で診療すべきとされる患者については精神科に紹介し、治療を実施するとした「ステップ」の仕組みも同時に組み込まれている。

わが国の一般身体科診療科における うつ病の発見と治療導入の現状

わが国の身体科診療科におけるうつ病有病率についての調査は、15年以上前に実施された研究ではあるが、その結果が示されている^{8,11)}。また、がん患者のうつ病有病率についての調査¹²⁾

英文タイトル：Collaborative Care in Primary Care to Identify and Treatment Depression
著者連絡先：稲垣正俊(岡山大学医学部精神神経学教室)
〒700-8558 岡山県岡山市北区鹿田町2-5-1
TEL : 086-235-7242 FAX : 086-235-7246
E-mail : brainpet@gmail.com
Corresponding author : Masatoshi Inagaki
Department of Neuropsychiatry, Okayama University Hospital
2-5-1 Shikatacho, Okayama Kita-ku, Okayama 700-8558, Japan

1) 独立行政法人国立精神・神経医療研究センター精神保

健研究所自殺予防総合対策センター
Masatoshi Inagaki, Tsuyuka Otsuki : Center for Suicide Prevention, National Institute of Mental Health, National Center of Neurology and Psychiatry
2) 独立行政法人国立精神・神経医療研究センター精神保健研究所神薬理研究部
Masatoshi Inagaki, Mitsuhiko Yamada : Department of Neuropsychopharmacology, National Institute of Mental Health, National Center of Neurology and Psychiatry
3) 長外科胃腸科医院
Takeshi Cho : Cho Surgical Clinic

*現所属 岡山大学医学部精神神経学教室

表1 かかりつけ病院の内科外来における精神疾患有病率調査の結果

	重み付け推定 有病率(%)	95%信頼区間 (%)
大うつ病エピソード現在(最近2週間)	7.4	8.2-20.0
自殺の危険現在(最近1ヶ月)「低」以上	12.7	6.6-18.9
躁病エピソード現在	-	-
軽躁病エピソード現在	0.8	0.0-2.4
パニック障害現在(最近1ヶ月)	-	-
広場恐怖現在	-	-
社会恐怖(社会不安障害)現在(最近1ヶ月)	-	-
外傷後ストレス障害現在(最近1ヶ月)	1.4	0.0-3.4
アルコール依存最近12ヶ月	5.4	0.3-10.5
アルコール乱用最近12ヶ月	-	-

対象者中に診断のつくものなかった有病率を推定していないため、「-」と記載している

(Inagaki M. et al. General Hospital Psychiatry, 2013を改変)

も実施されている。しかし、これらの病院は、精神科サービスのある総合病院や特定の疾患専門の病院で実施されたもので、精神科サービスのない病院や一般の診療所にそのままこれらの結果が外挿できるか不明であった。

そこで、我々は、精神科の併設していない(精神科サービスのない)病院の内科外来における、うつ病有病率調査を行った^{4,9)}。層別サンプリングのうえ、構造化診断面接を用いてうつ病有病率を調査した結果、大うつ病の時点有病率が7.4%という結果を得た(表1)。

うつ病有病率だけでなく、その後の自然経過についての情報を得るため、この調査をベースライン調査として、うつ病症状の経過についての縦断観察調査を実施した。その結果、うつ病症状のある患者の一部は6ヶ月後までに症状が軽快するが、全てのうつ病患者の症状が軽快するわけではなく、長期に症状が改善しない患者がいることが示唆された。同時に、うつ病でない患者の中からも6ヶ月後再調査をすると、新たにうつ病症状を有する患者も新たに出てくることも示された¹⁰⁾。

これらのうつ病を患う内科外来患者に対して、適切なうつ病治療・支援を提供するためには、少なくとも、医師を含む医療従事者がうつ病を疑い、可能性の高い患者に対してはうつ病の診断を

実施するもしくは精神科に紹介し、診断を受け、その後の治療に導入するなどの必要がある。しかし、身体科医師がどの程度うつ病に気づいているかといった情報がわが国ではこれまでになかった。そこで、同じく内科外来場面において、うつ病相当の患者に対して内科主治医が、精神科診断をつけているか否かを調査した⁹⁾。その結果、大うつ病相当の患者の約8割に対して、主治医は、「何らかの精神的な問題を抱えている」と判断する一方で、その診断を「不眠」とのみ診断し、「うつ病」もしくは「大うつ病」という診断をしていないという結果であった。この結果は、実際に、大うつ病相当の患者に対して、内科医師は抗うつ薬ではなく抗不安薬・睡眠薬のみを処方していたことから裏付けられた。背景には、うつ病という診断や更にはその治療は、内科の役割ではなく、精神科の役割だとするこれまでのわが国の医療制度があるのかもしれない。

わが国の身体科診療科医師の うつ病治療に対する考え方

かかりつけ医療場面や一般の身体科診療科場面においてうつ病を少なくとも疑い、必要に応じて治療または精神科に紹介するということが、わが

表2 一般身体科診療科医師のうつ病に対する態度(考え方)

調査項目において半数以上の医師が「同意」した項目
過去5年間に、私は、うつ病症状のある患者数の増加を目の当たりにしてきた看護師は、うつ病患者の支援に役立つ人となりうる(あなたの日々の臨床において)うつ病患者と共に取り組むのは重いことだもし、うつ病患者が抗うつ薬を必要とするなら、一般診療科医よりも精神科医が診るほうが良いうつ病患者に対する精神療法は、専門家に任せるべきだ
調査項目において半数以上の医師が「同意しなかった」項目
一般診療科で遭遇するうつ病の大部分は、薬物療法なしに改善するうつ病になるということはスタミナに乏しい人々が人生の困難に対処する方法だうつ病患者のニーズを扱うことは気楽なことだ
一般診療科の治療に反応しないうつ病患者に提供されるべきことは少しもない

(Ohtsuki T. et al. BMC Research Note 2012を改変)

国の身体科診療科の医師がどこまで実施すべきと考えているか、ということについて調査した所、ほとんどの医師が「うつ病診療は一般診療の対象ではない」と考えていた(表2)¹⁰⁾。これが、内科外来におけるうつ病患者に対して、医師がうつ病という診断をしない原因かもしれない。同時にこの調査では、医師は「看護師はうつ病診療の役に立つ人材となる」と考えていることも示している。この結果から、うつ病診療をかかりつけ医療場面や一般身体科診療科で実施するためには看護師等の役割を含めた体制がより実施可能性が高いと推測される。

一般身体科診療科におけるうつ病の 発見と治療導入のモデル案

わが国の精神科を併設しない病院の内科外来のうつ病有病率、医師のうつ病認識率、医師のうつ病診療への考え等と、既に海外で効果が実証されているうつ病スクリーニングと多職種協働ステップ治療に関する知見を元に、うつ病スクリーニングの実施、スクリーニング陽性となった患者に対する診断・ケースマネジメントとともに、かかりつけ病院場面において治療を実施する、もしくは精神科への紹介を行うというモデル案を作成した。そのモデル案を実施するための体制を構築するためには、身体科診療科内での準備、診療科の外部資源の確認と連携構築、患者への告知など、事前の準備が必要となる(表3)。今回は、身体科

診療科で既に診療に従事している看護師が中心となりスクリーニングとケースマネジメントを実施する案を作成した。

1) 診療科の内部の事前準備

医師、看護師、医療事務員等に、うつ病およびうつ病スクリーニングについての必要性を認識してもらうための研修を実施する。また、スクリーニング導入に必要な共感的なコミュニケーションスキルの訓練を実施する。そのうえで、うつ病スクリーニングの実施手順・ロジスティック等を医療従事者が集まり検討する。また、ケースマネジメントを実施する看護師は、これらに加えて、ケースマネジメントの実施手順を他の看護師、医師と検討する。

医療従事者だけでなく、患者に対しても、「体の病気の治療のためにはこころの健康が大切です。当院ではこころの健康についても気を配り、治療を行っていきます」などの内容で、うつ病スクリーニングの実施やケースマネジメント等を実施することの意義を事前に告知しておく。これにより、看護師によるうつ病スクリーニングや、スクリーニング陽性患者に対するケースマネジメントの導入に対する患者の抵抗感を和らげることができるかもしれない。

2) 診療科の外部との事前の連携準備

地域の医師会、地域保健対策協議会、自治体の精神保健に関する主管課にうつ病スクリーニング

表3 地域連携バス作成に必要な、一般身体科診療科内での準備と診療科外連携の準備バス(チェックリスト)

1. 診療科内の準備
(ア)診療科内スタッフへの基本的研修(うつ病に関する研修, コミュニケーションスキル訓練)
(イ)診療科内スタッフへのスクリーニング実施手順訓練
(ウ)担当看護師へのケースマネジメント実施手順訓練
(エ)診療科内スタッフでの実施体制の検討
(オ)患者教育・告知
2. 診療科外の資源との連携準備
(ア)保健所, 精神保健福祉センター, 包括支援センター, 精神科病院・診療所への連絡
(イ)うつ病の背景にある社会的問題に対する相談窓口の確認と必要に応じて連絡
(ウ)地域の精神保健の主管課, 医師会, 地域自殺対策協議会への報告
3. 事前予備的実施とモデルの修正
(ア)半日もしくは1日の予備実施とそこでの問題点・工夫点の検討とモデルの修正
4. スクリーニングの実施
(ア)6ヶ月に1度, 1ヶ月間に受診する全成人患者へのスクリーニングの実施
5. ケースマネジメントの実施
(ア)スクリーニング陽性患者へのケースマネジメントの実施(少なくとも6ヶ月間)
(イ)ケースマネジメントの中で実施する要素として, うつ病重症度, 身体疾患状況のモニタリング, 治療アドヒアランス, 生活のストレス因, 生活上の支援資源についての毎回の確認と, 必要に応じた適切な対応
(ウ)定期的な, 診療科内のスタッフで, ケースマネジメント実施中の患者についての事例検討
6. 診療科外の資源(保健師, 地域包括センター, 精神科)による支援とバックアップ
(ア)ケースマネジメント中に必要に応じた, 保健所, 地域包括支援センター, 精神科病院・診療所への紹介, 並診, 転院
(イ)定期的な, 保健所, 地域包括支援センター, 精神科病院・診療所と連携, 紹介を要する(した)事例についての事例検討会
(ウ)定期的な精神保健の専門家によるスーパービジョンの実施

※本表は, 実施に際してのバス図の前提として必要な事前準備のチェックリストとしての姿となっている。実施可能性, 効果および制約がまだ確認されていないモデル案の段階の図である。

とケースマネジメントの実施, 必要に応じて院外の資源の活用を行う等の旨を連絡する。これは, 診療科の外部との連携の構築や強化の基盤となる。患者が来院を中断した場合で, しかも電話等での連絡ができず, 必要なケースマネジメントができない場合に備えて, 地域の保健師や地域包括センターのケアマネジャー等に対して事前に実施について説明を行い, 必要に応じて訪問による見守りの依頼や介護支援の検討を行うための共同での事例検討を計画する。

また, うつ病の背景に存在しやすい様々な社会的問題についての相談支援窓口の連絡先リストを作成する。これについては, 自治体の主管課や精神保健福祉センター, 保健所などが既に作成している場合はそれを活用することができる。

3) 看護師中心の多職種協働によるうつ病スクリーニングの実施

うつ病を疑った患者に対してのみうつ病スクリーニングを実施するという方法では, 見逃しが生じる可能性があるため, 海外のメタ分析の結果を元に, スクリーニングはシステムティックに全例に実施することとした。患者の受診の度に毎回実施するのはロジスティックの面から困難であると予想されること。全ての患者に実施したか否かの記録とその参照が実臨床の中では困難だと予想されるため, 代替の方法として, 定期的に, ある1ヶ月間に受診する成人患者全員にスクリーニングを実施するという案を検討し, 採用した。かかりつけ病院として機能している病院においては, 多くの患者が2週間に1度から1ヶ月に1度程

度での頻度で受診していると見積り, 1ヶ月間の全患者を対象とすることで多くの割合の患者に対して実施できると考えた。また, 6ヶ月経過すると, うつ病のない患者からもうつ病が新たに生じる可能性を示す結果があることから, 少なくとも6ヶ月に1度は1ヶ月間全例へのうつ病スクリーニングを実施することとした。20歳以下の患者は, うつ病陽性となった場合の対応が困難な場合があること¹⁵⁾, かかりつけ病院として定期的な利用が少ないことから, 対象から除外した。

うつ病スクリーニングツールとして, Patient Health Questionnaire-9^{7,13)}という自記式の9項目のうつ病スクリーニングツールを採用した。海外においてプライマリ・ケア場面でスクリーニング性能が高いことが示され, 多く使用されていること, わが国の一般病院内科外来患者においてもその性能が確認されていること⁵⁾, 質問数が9問と少なく短い時間で実施できること, 希死念慮を尋ねる項目が入っていること, スクリーニングだけでなくその後の重症度のモニタリングに使用可能なことを根拠に採用した。スクリーニング陽性の判断は, 10点以上もしくは, はじめの2問のどちらかを含み5項目以上で該当する場合とした。わが国の一般内科外来で行った調査からは, この陽性基準は特異度が十分高いが, 感度が劣る可能性が示されているが⁵⁾, 今回は, 擬陽性を減らすこと, より重症の患者から優先してケースマネジメントを実施することを考慮し採用した。他の場面では, より感度が高い(しかし, 特異度に劣る)陽性基準を採用することも検討する必要がある。

4) 看護師中心の多職種協働によるうつ病スクリーニング陽性患者に対するケースマネジメントの実施

ケースマネジメントを実施する対象者は, 先のうつ病スクリーニングで陽性となった患者とした。うつ病有病率が7-8%であることを考慮すると^{4,9)}, 1ヶ月間にうつ病スクリーニングの対象となる患者が400名である場合, 予想される陽性患者数は多くとも30名程度と計算され, 看護師によるケースマネジメントの実施が可能人数だと見積もった。ケースマネジメントにおいては, 患

者に対してうつ病についての心理教育を実施するとともに, うつ病重症度, 背景にあるストレス因, 治療アドヒアランスなどの患者の状態を定期的に観察し, 必要に応じた治療や支援の提供ができることを目的とした。特に, 来院の中断, フォローアップからの脱落, 治療の中断を防ぐために, 定期的な受診やケースマネジメントができていないか否かに注意を払うこととした。そのため, ケースマネジメントの対象となった患者のリスト台帳を作成し, 受診日程や予約の記録, ケースマネジメント実施の内容を記録する。カルテへの記載のみでは, 患者の来院がない場合にはそのカルテを参照する機会がないため, 患者が受診を中断したことに気づきにくいという問題があるため, 毎日の打ち合わせで, 台帳を基に患者の受診状況と予定を確認することとした。

5) 精神科医師によるスーパービジョン

本来は, 地域の精神科病院や精神保健福祉センター等の専門家による実施が, 連携を高める観点や地域の利用可能な資源へ精通しているという観点からも理想である。しかし, 地域の精神科専門家資源が少ない場合など, 実施が困難な場合には, 大学等の研究・教育機関に所属する医師や, 地域外の精神保健の専門家にスーパービジョンを依頼しなければならない場合もあるかもしれない。ケースマネジメントに対するスーパービジョンだけでなく, 医師の処方や診断についても精神保健の専門家による助言・指導を依頼するモデルが必要だと判断した。

今後の課題

これまでに得られた知見を元に, わが国のかかりつけ機能を有する身体科診療科において実施を考慮するモデルを検討してみた。今後, モデルの手順書の作成, 実施可能性について検討, モデルの修正を経て, 効果および有害事象の検討が必要となる。また, 均てん化を考慮すると費用対効果や実施に向けての研修制度の確立など長期的ビジョンに沿った計画も必要となろう。

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abstract

Collaborative Care in Primary Care to Identify and Treatment Depression

Masatoshi Inagaki^{1,2)}, Tsuyuka Otsuki²⁾, Takeshi Cho³⁾, Mitsuhiko Yamada⁴⁾

Many of depressed patients do not receive appropriate care. Although some of the patients consult to physicians as their primary care, many of the depressed patients in the primary care are not identified as having depression, and thus, cannot receive appropriate depression care. Given the situation, we discussed a model to identify depressed patients in the primary care settings and then to introduce the depressed patients to appropriate care. Also we discussed required preparations to perform the model including establishing collaborations among primary care and other professionals.

We developed the model based on findings regarding prevalence of depression in primary care settings, validity and utility of screening tools, attitudes of physicians toward depression in Japan, and findings obtained in other countries, such as effectiveness of collaborative stepped care model.

As a result, feasibility of a nurse-centered collaborative stepped depression care model has been discussed. The model includes periodical systematic performance of depression screening, case-management for screening positive patients with probable depression, and consultation with mental health professionals. Also, establishing collaborations among other professionals outside of the primary care is required before starting the depression care model.

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¹⁾ Department of Neuropsychiatry, Okayama University Hospital

²⁾ Center for Suicide Prevention, National Institute of Mental Health, National Center of Neurology and Psychiatry

³⁾ Cho Surgical Clinic

⁴⁾ Department of Neuropsychopharmacology, National Institute of Mental Health, National Center of Neurology and Psychiatry

■研究報告

一般身体科かかりつけクリニック外来患者全例を対象とした 定期的なうつ病スクリーニングの実施可能性

—後方視的、量的および質的検討—

長 健¹ 大槻 露華² 原田千恵美³
 島山みゆき⁴ 三宅 潤子⁵ 光成 郁子⁶
 五阿弥倫子⁷ 山田 光彦⁸ 稲垣 正俊⁹

抄録：近年、わが国でも、かかりつけ医療機関において、うつ病を発見し、適切な治療に導入する必要性が認識され始めた。そこで、臨床として定期的なうつ病スクリーニングとスクリーニング陽性患者に対する看護師中心のケースマネジメントを実施したAクリニックの臨床経験を後方視的に観察し、うつ病スクリーニングの実施可能性を検討した。事前にクリニックスタッフへの研修を実施し、院内・院外における連携の構築、スクリーニング陽性患者に対する支援体制の構築を行い、スクリーニングを実施した。その結果、患者の9割にスクリーニングが実施でき、3～5%の患者が新たに中等症以上のうつ病と判断され、その後のケースマネジメントに導入された。これらのことから、事前準備を行うことで、かかりつけ医療機関において定期的なうつ病スクリーニングを実施することが可能と考えられた。

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Key words : depression, screening, feasibility, primary care, clinical path

I. はじめに

WHOによると世界中で少なくとも3億5千万人がうつ病を抱えていると見積もられている¹⁾。

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 Feasibility of periodic depression screenings for outpatients in primary care clinic: a retrospective qualitative and quantitative observational study.
 長外科胃腸科医 院
 〒720-2413 広島県福山市駅前町法成寺4丁目
 Takeshi Cho, M.D., Ph.D., Chiemi Harada, Ns. Miyuki Harakeyama, Ns. Junko Miyake, Ns. Ikuko Mitsumori, Ns. Michiko Goami, Ns.; Cho Surgical Clinic, 4-1, Hon-jouji, Ikkiya-cho, Fukuyama-shi, Hiroshima, 720-2413 Japan.
 国立精神・神経医療研究センター精神保健研究所自裁

WHOと世界銀行が定めた障害調整生命年で評価した健康の指標の調査では、うつ病は2030年には世界で最も健康を損なう障害となると推測され、わが国を含めた中高所得国では2004年にすでに最も大きな障害であったと報告された²⁾。

予防総合対策センター
 Tsuyuka Ohtsuki, Ph.D.; Center for Suicide Prevention, National Institute of Mental Health, National Center of Neurology and Psychiatry.
 国立精神・神経医療研究センター精神保健研究所精神薬理研究部
 Masahiko Yamada, M.D., Ph.D.; Department of Neuropsychopharmacology, National Institute of Mental Health, National Center of Neurology and Psychiatry.
 岡山大学病院精神科神経科
 Masatoshi Inagaki, M.D., Ph.D.; Department of Neuropsychiatry, Okayama University Hospital.

わが国の地域住民における大うつ病性障害の12ヵ月有病率は2.1%と報告されているが、そのうち、何らかの医療機関を受診していたうつ病患者の約1/3の受診先は精神科ではなく一般身体科であった³⁾。このことから、精神科以外の診療科においてもうつ病患者が相談支援を求めていることが窺える。実際、地方郡部に位置する一般病院内科外来では、大うつ病性障害の有病率が7.4%と報告されている⁴⁾。地域においてかかりつけ医として機能している身体科の診療場におけるうつ病有病率は高く、このような場面は、適切なケアや支援に結びついていないうつ病患者を発見し、適切なケアや支援に結びつけることができるセッティングであるといえる。

プライマリケアや総合診療医制度のある英国や米国等では、軽症うつ病についてはプライマリケア場面で多職種協働による段階的なアルゴリズムに沿った治療が推奨されており、その成果も報告されている⁵⁾。これまでの先行研究を対象としたメタ解析から、多職種協働の複合的な介入の各要素の中でも、精神科の専門知識を有するケースマネージャーの配置や定期的なケースマネジメントおよび精神科医によるそのスーパービジョンがうつ病症状の改善に有効であり、患者の全例登録も必要であることが示されている⁶⁾。

一方、プライマリケア制度のないわが国では、各専門領域の診療科で各疾患が治療されており、これまでは、身体科でうつ病を発見し治療に導入することは積極的に推奨されてこなかった。実際に、わが国の一般身体科医を対象としてうつ病に対する態度を調べた研究において、一般身体科医の多くはうつ病は一般診療の対象ではないと考えており⁷⁾、その考えが強い医師ほど、日常診療においてうつ病治療は実施可能でない、うつ病診療を希望しないと回答していた⁸⁾。また、一般病院の内科外来において、受診患者のうつ病を医師がどの程度認識していたかを調査した結果、内科医はうつ病患者の約1割しかうつ病があると気づいていなかった⁹⁾。これらのことから、かかりつけ医療機関においても、うつ病スクリーニングを実施し、うつ病を発見し適切な支援へとつなげる必要性が高い。

これまで、一般身体科かかりつけ医療機関として機能しているAクリニックにおいて、うつ病の可能性のある患者を把握し、適切なケアや支援に結びつける試みがなされてきた。Aクリニックでは、近隣医療・保健機関との連携構築とクリニック内の事前準備のもと、定期的なうつ病スクリーニングとスクリーニング陽性患者に対する看護師中心のケースマネジメントからなるクリニカルパス¹⁰⁾が作成され、すべての外来患者を対象に多職種協働による段階的なうつ病診療が試みられている。そこで、本研究では、一般身体科かかりつけクリニック外来患者全例を対象としたうつ病スクリーニングの実施可能性と克服すべき課題を把握するため、Aクリニックにおける「外来患者全例を対象とした定期的なうつ病スクリーニングとスクリーニング陽性患者に対する看護師中心のケースマネジメント」の臨床経験について、その一部である「定期的なうつ病スクリーニング」部分についての経験を後方視的に観察し量的および質的に検討した。なお、うつ病スクリーニング陽性患者に対するケースマネジメント部分の実施可能性については、別の機会に発表する。

II. 方法

1. セッティング

Aクリニックは、広島県の東部に位置し、外科、整形外科、胃腸科、皮膚科、肝臓科を標榜する無床診療所である。医師1名、看護師5名、事務職員4名が医療スタッフとして従事している。外来診療中には、医師1名、看護師4名、事務職員4名が常駐している。1ヵ月間の20歳以上の受診患者数は300名超である(2012年4月および10月の状況)。1日の受診患者数は約65名である(2012年4月および10月の状況)。

2. クリニカルパスの作成手順とその内容

クリニカルパス¹¹⁾は、国立精神・神経医療研究センターに所属する精神保健の専門家らの支援のもと、Aクリニックの医療従事者等との協働により作成された。国内外のエビデンスに基づき作成されすでに論文として公表されている看護師中

表1 スクリーニングおよびその後のケースマネジメント実施手順の概要(文献5を参照、一部改変)

1. 診療所内の準備
 - (ア) 診療所内スタッフへの基本的研修(うつ病に関する研修, コミュニケーションスキル訓練)
 - (イ) 診療所内スタッフへのスクリーニング実施手順訓練
 - (ウ) 担当看護師へのケースマネジメント実施手順訓練
 - (エ) 診療所内スタッフでの実施体制の検討
 - (オ) 患者教育・告知
2. 診療所外の資源との連携準備
 - (ア) 保健所, 精神保健福祉センター, 地域包括支援センター, 精神科病院・診療所への連絡
 - (イ) うつ病の背景にある社会的問題に対する相談窓口の確認と必要に応じて連絡
 - (ウ) 地域の精神保健の主管課, 医師会, 地域自殺対策協議会への報告
3. 事前準備の実施とモデルの修正
 - (ア) 半日もしくは1日の予備実施とそこでの問題点・工夫点の検討とモデルの修正
4. スクリーニングの実施
 - (ア) 6ヵ月に1度, 1ヵ月間に受診する外来患者へのスクリーニングの実施
 - (イ) 医師への結果のフィードバックと医療従事者間での共有
5. ケースマネジメントの実施
 - (ア) スクリーニング陽性患者へのケースマネジメントの実施(少なくとも6ヵ月間)
 - (イ) ケースマネジメントの中で実施する要素として, うつ病重症度, 身体疾患状況のモニタリング, 治療アドヒアランス, 生活のストレス因, 生活上の支援資源についての毎回の確認と, 必要に応じた適切な対応
 - (ウ) 定期的に, 診療所内のスタッフで, ケースマネジメント実施中の患者についての事例検討
6. 診療所外の資源(保健師, 地域包括支援センター, 精神科)による支援とバックアップ
 - (ア) ケースマネジメント中に必要に応じた, 保健師, 地域包括支援センター, 精神科病院・診療所への紹介, 転院
 - (イ) 定期的な, 保健師, 地域包括支援センター, 精神科病院・診療所と連携, 紹介を要する(した)事例についての事例検討会
 - (ウ) 定期的な精神保健の専門家によるスーパービジョンの実施

心の多職種協働ケアモデルが, 今回のクリニカルパスの理論的基盤として参照された。本クリニカルパスの概要は以下の通りである(表1: 論文を参照, 一部改変)。クリニカルパスは事前準備, スクリーニング, およびスクリーニング陽性患者に対するケースマネジメントの実施から構成されている。以下にスクリーニング部分について詳述する。ある1ヵ月間に受診する20歳以上, 認知症のないすべての患者を対象として Patient Health Questionnaire-9 (PHQ-9) を実施する。PHQ-9は自己記入式の9項目からなるうつ病スクリーニングツールで, 日本のかかりつけ機能を有する病院内科外来においてその性能が確かめられている。PHQ-9によるスクリーニングは, 過去に報告された基準に従い, 1項目目もし

くは2項目目のどちらか少なくとも一方を満たし, 合計で9項目中5項目以上を満たす場合をスクリーニング陽性とする。同時に, 各項目の合計得点を算出し, 重症度の指標として利用する。医師は診察時にスクリーニングの結果を確認する。スクリーニングで陽性と判断された患者は, その後のケースマネジメントの対象者となり, 定期的に看護師がPHQ-9によるうつ病の重症度, ストレス要因, 治療遵守状況等をフォローアップする。また, PHQ-9において, 上記の陽性基準を満たさなくとも, 医師, 看護師が必要と判断した場合には, その後のケースマネジメントの対象となる。うつ病スクリーニングはあらかじめ定めた1ヵ月間実施するが, これを6ヵ月毎に実施する。ケースマネジメントは少なくとも6ヵ月間実

施し, 必要に応じて延長する。なお, PHQ-9はファイザー社ホームページから「ここからからだの質問票」としてダウンロード可能。また, 国立精神・神経医療研究センター監修による身体科におけるうつ病スクリーニング検査・研修・臨床研究ソフト「身体疾患患者精神の支援ストラテジー」(NOVA 出版)からも入手可能。

3. 事前準備

クリニカルパスに従い, 事前準備として, 院内の医療従事者に対して, 専門家によるうつ病とその治療に関する研修, うつ病スクリーニングとその後のケースマネジメントに必要なコミュニケーションスキルの研修が実施されていた。また, 院内で事前に患者に対して, こころの状態についての問診を行う旨の告知が, ポスターの掲示により行われた。加えて, 地域の医師会において本クリニカルパス使用についての議論を経ることで, 地域の関連する医療機関の協力を得る基盤が強化されていた。地域行政の精神障害・精神保健に関する主管課との打ち合わせが行われ, クリニカルパス使用開始予定であることが事前に報告されていた。保健所との打ち合わせにより, ケースマネジメントで必要となる地域訪問等の協力が得られていた。さらに, 地域を担当する広島県精神保健福祉センターが作成していた心理社会的な支援や相談窓口のリストを事前に入手していた。

4. クリニカルパス使用に際しての倫理的配慮

Aクリニクにおいて, 本クリニカルパスは, 通常の診療業務として実施されたが, 新たな診療行為であったため, 広島県府中地区医師会生命倫理委員会の承認を得て行われていた。また, その使用開始に際しては, 公告文の掲示により, 患者に対してこころの状態について問診を行う旨が伝えられていた。また, 使用開始前には対象となる患者にその必要性が説明され, 本人から口頭による同意を得た上で使用された。

5. 調査内容

クリニカルパスを用いたうつ病スクリーニングの実施可能性を検討するための指標として, スク

表2 対象者背景

	1回目スクリーニング (2011年4月1日 から4月30日)	2回目スクリーニング (10月1日 から10月31日)
年齢: 中央値(範囲) (歳)	70 (22-96)	71 (31-97)
性別(女性): 人数(%)	150 (51.5%)	156 (56.5%)
身体疾患病名(上位3 疾患, 重複あり): 人数(%)		
高血圧症	148 (50.9%)	150 (54.3%)
腰痛症	84 (28.0%)	96 (34.9%)
脂質異常症	80 (27.5%)	77 (27.9%)
過去4ヵ月間の受診 回数: 中央値(範囲)	6 (1-112)	8 (1-106)

リーニングの実施人数と対象者中の実施率を評価項目と臨床データを集計した(2011年4月および2011年10月)。さらに, クリニカルパスの使用開始後に, 医療従事者から, 主観的な負担度, 他の業務への支障, 実施に伴う利点, その他気づいた点について聞き取り調査を行い, 得られた知見をもとに, 医療従事者と研究者がグループディスカッションを行い, 意見を集約した。

6. 倫理的配慮

本研究では, 個人を特定できる情報を収集しなかった。また, 本研究におけるデータ集計および検討結果の公表に関して, 広島県府中地区医師会生命倫理委員会の承認を得ている。

III. 結 果

1. クリニカルパスに基づくうつ病スクリーニングの実施可能性—量的検討—

1ヵ月間のスクリーニングおよびその後6ヵ月間のケースマネジメントのサイクルが2011年4月から開始され, その後2011年10月, 2012年4月, 2012年10月と継続していた。本研究では, 2011年4月および10月に実施されたうつ病スクリーニングの結果について調査した。以下, 2011年4月お

表3 1回目および2回目のスクリーニング実施者数

	1回目スクリーニング (2011年4月1日 から4月30日)	2回目スクリーニング (10月1日から 10月31日)
受診全患者数	435	
スクリーニング実施 不適格者数	124	104
20歳未満	8	16
家族のみの受診	30	17
春宅往診	11	8
認知症	71	57
身体的に重篤	4	6
スクリーニング実施 適格者数	311 (100%)	308 (100%)
実施漏れ	20 (6.4%)	32 (10.4%)
コンタクトミス	13 (4.2%)	25 (8.1%)
拒否	7 (2.3%)	7 (2.3%)
実施人数	291 (93.5%)	276 (89.5%)

および10月の実施をそれぞれ1回目、2回目と表示した。

表2に、実施対象者の背景情報を示した。実施対象者の多くが60歳以上で、高血圧症、腰痛症、脂質異常症といった慢性疾患を患っていた。過去4ヶ月の受診の頻度は、2週間に1〜2度の頻度で受診していた換算となる。

事前に定めた対象者基準に基づく適格者のうち、実施が可能であった者の割合を表3に示した。また、実施が不可能であった理由についても表3に示した。約9割(1回目と2回目合わせて適格者619名中567名、91.6%)の患者に実施できた。

1回目は全外来受診患者435名から不適格者124名を除き、うつ病スクリーニング実施の適格者は311名であった。そのうち、スクリーニングの実施の依頼ができなかった(コンタクトミス)13名、拒否した7名を除き、291名にスクリーニングが実施されていた。その結果、14名がうつ病スクリーニング陽性と判断され、うつ病スクリーニングの結果は陰性であったが心理社会的な問題を抱えた独居の患者2名が医師の判断により加えら

表4 1回目および2回目のスクリーニングスコアの人数分布

	1回目スクリーニング (2011年4月1日 から4月30日)	2回目スクリーニング (10月1日から 10月31日)
PHQ-9スコアの 人数分布		
20-27点	5 (1.7%)	1 (0.4%)
15-19点	7 (2.4%)	4 (1.4%)
10-14点	12 (4.1%)	17 (6.2%)
5-9点	57 (19.6%)	38 (13.8%)
0-4点	210 (72.2%)	216 (78.3%)

れ、16名がその後のケースマネジメントに導入されていた。2回目は実施期間中の全外来受診患者412名中、308名がスクリーニング実施適格者であったが、25名に実施の依頼ができず、7名に拒否され、276名にスクリーニングが実施できた。その結果、9名がうつ病スクリーニングで陽性と判断され、1回目のスクリーニングですでにケースマネジメントに導入されていた患者1名を除き、また、医師の判断で1名が追加され、1回目に導入された16名に加えて、さらに新たに9名がケースマネジメントに導入されていた。なお、1回目のスクリーニングと2回目のスクリーニングの両方を受けた患者が496名おり、2回目のスクリーニングが初めてのスクリーニングであった患者は80名であった。表4にスクリーニング得点の分布を示した。一般的に中等症以上のうつ病として判断される10点以上の得点の患者が約8%含まれていた。重症とされる15点以上に限定しても1.8-4.1%となっている。

なお、詳細を記述しないが、その後の2012年4月、10月、2013年4月にも、同クリニックによるうつ病スクリーニングを継続して実施している。

2. クリニカルパスに基づくうつ病スクリーニングの実施可能性—質的検討—

医師1名、看護師5名、事務職員4名の全員からクリニックパスの使用開始後に聞き取り調査を

行うことができた。使用開始前には忙しい外来で実施可能か、すべての患者にスクリーニングを実施できるか、心理的問題について触れられたくない患者がいるかもしれない、スクリーニングにより新たな問題が発見された場合にその対応に苦慮しないか、特に希死念慮についての訴えに対して適切に対応できるか、という懸念があったが、スクリーニング実施後には、スクリーニング実施に関する懸念が軽減し、これらに対して、対処できたという意見が多く得られた。さらに、クリニックパスの使用開始後には、患者の背景にある様々な心理社会的な問題に新たに気づくようになり、問題解決が可能となったと多くの医療従事者が認識していた。また、積極的にこれら心理社会的問題について質問するようになったと答えた。

また、クリニックパスの使用に際して他の業務への支障を医療従事者が感じることもなく、また、人員を増員することなく、うつ病スクリーニングが実施されていた。臨床業務の時間が伸びるなどの影響も認められなかった。数名の患者がスクリーニングを拒否したが、患者からスクリーニングの実施に対する拒絶的な意見もなく、診察の待ち時間が増えたなどの苦情もなかった。

しかし、新たにうつ病スクリーニングで陽性と判断される患者がほとんどいなくなっても継続するのか、といった長期的な展望についての計画を立てていく必要性が医療従事者から指摘された。新たにうつ病スクリーニング陽性と判断される患者が少数となる場合には、実施に要する労力に比べ、得られる患者の利益が相対的に小さくなるため、一定の間数を実施した後には、より労力の少ない効率的な方法を検討すべきだとの意見が挙がった。

IV. 考 察

本調査では、うつ病スクリーニングが定期的に複数回実施された経験にもとづいた結果を示した。全受診者を対象にスクリーニングを行い、そのうち、今回検討した2回のスクリーニング期間中、スクリーニングの実施を予定した患者の約9割に実施できていた。スクリーニングを2回実施

した後に看護師に対して行った調査から、スクリーニングは抵抗感や不安、負担感の増加もなく実施できていた。

また、各スクリーニング期間中にそれぞれ、うつ病疑いの患者が新たに同定されており、その後のケースマネジメントに引き継ぐことができていた。これまでのうつ病スクリーニングの効果に関する知見からは、スクリーニングの実施のみでは患者の症状の改善効果は期待できないが、その後の有効な治療法と組み合わせることで効果が期待されると報告されている。今回は、うつ病スクリーニングに続き、スクリーニング陽性者に対する看護師中心の多職種協働のケースマネジメントを組み合わせており、本報告に加えて、ケースマネジメントの実施可能性についての検討が今後必要である。

今回のスクリーニング手順においては、過去6ヶ月間のうつ病スクリーニングの有無を患者毎に確認する作業が不要で、すべての患者に同一の手順でスクリーニングを実施できるため、その期間中にスクリーニング実施の基準を満たす患者に対しては見逃しが少なく実施可能であった。しかし、1回目と2回目のスクリーニングで重複して実施した患者以外に、2回目初めてうつ病スクリーニングを実施された患者および、1回目ではスクリーニングを受けたが、2回目の期間中には受けていない患者も一定数いた。これらの点は、6ヶ月毎の1ヶ月間に受診した患者にうつ病スクリーニングを実施するという本クリニックパスの限界であり、今後解決すべき問題である。

クリニックパスの使用開始に際して、事前準備を行うことで、医療従事者がスクリーニングを実施する際の抵抗感や負担感が軽減した可能性が推測される。また、スクリーニング陽性患者に対するその後のケアとして、看護師中心のケースマネジメントに関するクリニックパスが作成されていたことで、スクリーニングにより陽性患者が特定された際にどう対処してよいかという懸念が軽減できたのかもしれない。スクリーニング陽性患者のうつ病が重症の場合には、精神科病院への紹介・入院や、必要に応じて地域保健師の訪問等が活用できる枠組みが準備されたことも、医療従事

者のスクリーニング実施の負担の増加につながらなかった理由かもしれない。

定期的な受診を要する慢性身体疾患を抱える高齢者がかかりつけ病院として受診している一般病院内科外来場面では、PHQ-9うつ病スクリーニングの9項目中5項目以上の基準を適応した場合、その感度は0.82、特異度が1.0という結果が示されている¹⁾。また、同場面において、スコア10点以上という基準では、感度0.55、特異度0.98と報告されている²⁾。Aクリニックで使用開始となったクリニカルパスにおいては、これら基準を用いてスクリーニングが行われている。その高い特異度から、うつ病スクリーニング陽性と判断された患者のほとんどが大うつ病性障害と推測される。一方で、その低い感度を考慮すると、大うつ病性障害であるにもかかわらず偽陰性の結果を示す例も存在すると考えられる。実際、一般病院内科外来場面における大うつ病性障害の有病率が7%程度であったことを考慮すると、Aクリニックではスクリーニング陽性と判断された患者が比較的少なく、この結果は、いくつかの症例が見逃されている可能性を示しているのかもしれない。診療場面毎にケースマネジメントの実施が可能な人数にもよるが、特異度が低くとも、より感度が高いカットオフ基準を用いた判断をする必要があるかもしれない。しかし、逆に、今回のカットオフ基準では、見逃される患者のうつ病は軽症で、より重症の患者がスクリーニング陽性として残りやすいとも考えられ、積極的な支援を強く必要とする患者から、順に、支援につなぐことができたとも考えられる。しかし、効果に関する検討は不十分であり、今後必要な課題と考えられる。

Aクリニックは、1ヵ月間の20歳以上の受診患者数が300名超であるが、今回採用したPHQ-9のスクリーニング陽性基準を用いると、1回目に14名、2回目に9名が1ヵ月間に陽性と判断され、ケースマネジメントの実施対象者となった。14名と9名を合わせても23名であり、1人の看護師がその後のケースマネジメントを実施可能な人数内にとどまっている。この規模の医療機関においては、ケースマネジメントのために必要な人材は1から2名という計算となり、逆に考えると、

ケースマネジメント可能な対象者数をあらかじめ算定し、うつ病スクリーニングのカットオフ基準を厳しくする、もしくは逆に低くし、より重症の患者のみ、もしくはより軽症の患者までスクリーニングにより発見するという調節が医療機関毎に可能であり、必要だろう。

本報告では、事前に作成したクリニカルパスにもとづき定期的なうつ病スクリーニングを実施したAクリニックにおける経緯をもとに、その実施可能性について検討した。院内だけでなく院外の資源との連携構築を含めた事前準備と、その後のケースマネジメントが組み合わさった中で、一般身体科の無床診療所においても看護師を中心としたうつ病スクリーニングが実施可能であることが示された。

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3 東京女子医科大学病院でのスクリーニングの実際

東京女子医科大学循環器内科 助教 同 准教授
 鈴木 豪 すずき つかし 志賀 剛 しが つよし
 同 主任教授・副院長
 萩原 誠久 はぎわらの ぶひさ

スクリーニング実施の背景

いくつかの国内外での先行研究。報告から循環器疾患における抑うつ¹の頻度は約15～20%前後であるといわれています^{1,2}。また、うつは心血管イベントとの関連においても独立した予後悪化因子であることが報告されています^{3,4}。対象疾患群は海外からの報告では虚血性心疾患を対象とした大規模試験が多く、最もエビデンスが豊富です。また、近年は心不全においても抑うつ⁵死亡または再入院といったイベントとの関連性も報告されてきました⁶。

このような多くのエビデンスの蓄積から、アメリカ心臓協会(AHA)は2008年にScience Advisoryという形で循環器疾患におけるうつ⁷のスクリーニングを推奨するに至りました⁶。うつ⁸のスクリーニングツールとして開発されたPHQを用い、PHQ-2およびPHQ-9(p.90 図1)の2段階スクリーニングにおいて、感度52%、特異度91%の精度で検出した群において心血管イベントの相対危険度は1.41であるとしています⁷。本スクリーニング自体が心血管疾患の予後を改善するという直接的なエビデンスはありませんが、うつ⁹自体が独立した予後悪化因子であり、何かしらの形でうつ¹⁰のスクリーニングを行い適切な介入を検討することは、患者さんのQOLにも関連すると考えられ重要と思われる。

しかしながら、わが国ではPHQの使用経験が少なく、一部の施設でその頻度などの報告が散見されるのが現状です。今回、東京女子医科大学病院において取り組んでいる循環器入院患者さんに対するうつ¹¹のスクリーニングについて概説し、具体的事例を紹介するとともに、今後のわが国での循環器領域での心理精神的問題の取り組みの手がかりを検討したいと考えます。

東京女子医科大学病院でのスクリーニングのとらえ

1. これまでの流れ

まず、当施設での先行研究の流れを見ていきます。当施設では2006年よりSDS (self depression scale) という20問の自記式アンケートを入院患者さん全員に配布し、初めてうつ¹²のスクリーニングを行った経験があります。その結果、SDSスコア>60(中等度以上)の抑うつ¹³は約22%におよび、うつ¹⁴群では有意にその後の心血管イベントが多いことを2011年に報告しました¹⁵。

2. PHQ-9 への移行

しかし、SDSは20問という質問数であり、患者さんの回答に関する負担やアンケートの回収率・脱落率に問題を残したため、当施設では新たなスクリーニングツールを検討しました。PHQ-9はわずか9問で、SDS同様自記式アンケートとして使用可能であり、日本語版での使用も検証されたツールです。当施設では本アンケートを用い、入院患者さんにおけるスクリーニングを行っています(図1)。また、当施設では入院早期にアンケートをとっていたため、陽性者に対しては退院後約1カ月に再度検査を行うこととしました。循環器疾患では疾患により引き起こされる一過性の心因反応(適応障害)も多く、PHQ-9スコア10以上ですぐに専門家への依頼という対応には限界があると考えたためです。

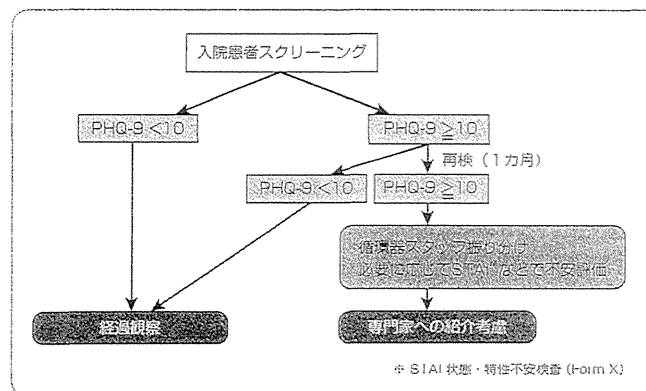


図1 当施設での入院患者さんへのスクリーニング

3. 結果

当施設入院患者さんを対象とした360例ではPHQ-9 \geq 10を満たす症例は約15%でした。また、退院後同一症例に対して再度外来にてPHQ-9を施行したところ、約30%は再度スコアが10を超えて陽性でした。逆にいえば、70%の患者さんにおいてスコアの改善が見られたことになります。

ケーススタディ：スクリーニング～介入までの実際

症例：61歳、女性

居住環境：独居

学歴：高校卒、現在は離職している

主訴：失神、めまい

診断：他施設で肥大型心筋症と診断されたが、失神を来し精査で入院となった

検査：心臓カテテル検査、ヘッドアップティルト試験、ホルター心電図検査などを予定

経過：入院時、PHQ-9スクリーニングでは19点と高値であった。20点近くの高値であったため、主治医と打ち合わせの上面談を行った。2年前に最愛の実母を脳梗塞で、患者の入院5カ月前に実父を腹部動脈瘤破裂でなくすなどのエピソードがあった。興味の消失、抑うつ気分、くよくよと考えるなど、その他の集中困難がみられ、今回入院することとなり、自身の身体に不安が強い様子であった。なお、自傷行動や自殺企図はみられなかった。スクリーニングと面談によりうつ病の可能性が強く考えられたため、患者に併診の形で「こころの専門家」にもみてもらうことを提案したところ、本人の希望もあったため、本インタビューの2日後、当院リエゾン科にコンサルトすることとなった。

専門家に受診後、うつ病または気分変調症の診断で一時抗不安薬（メイラックス[®]）が開始されたが、抑うつ気分の改善乏しく、SSRI（ジェイゾロフト[®]）が開始となった。

本症例の振り返り：入院前の比較的短期間に家族との死別といったきっかけがあることが考えられたが、患者の話からは抑うつ気分は2年前から先行していた。循環器での精査終了後、NMS（神経調節性失神）の診断で外来で経過観察している。この症例では退院後1カ月後のPHQ-9スクリーニング再検査で22点とスコアが上昇しており、「入院」による一過性の心因反応や適応障害の範疇ではないと判断した。

おわりに

PHQ-9は多くのスクリーニングツールの中でも質問数が9問と比較的少なく、回答者の負担を少なくして施行できるツールです。AHAの推奨では、PHQ-9の前にPHQ-2を施行し、陽性者に対してPHQ-9を施行する2 step screeningのフローチャートとなっています⁷。

現在、わが国では身体科でのスクリーニングシステムとしてはまだまだ十分な普及を見えないのが実情です。理想としては、身体科においてPHQのようなツールを使用し面談を行って、専門家への依頼の判断を行うところまでが達成されるとまずはよいと考えられます。ただし、一定の頻度でスコア10点以上の症例が存在するため、10点でのカットオフでの専門家への紹介の妥当性、PHQ-2の使い方など、実臨床ではまだ議論が必要となることが多く、身体科でもツールの使用にあたって基本的知識があることが今後は望まれると考えられます。

スクリーニング実施の key point

- ・うつは心血管疾患の独立した予後悪化因子である
- ・スクリーニングは簡便なツールが望ましく、現在PHQ-9が推奨されている
- ・一度のスクリーニング結果のみでは限界があるため、経時変化をみることも重要である

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循環器医療とうつ病等精神疾患

東京女子医科大学 循環器内科
鈴木 豪 先生

■循環器疾患におけるうつ病

循環器疾患では、冠動脈疾患の患者さんの16～23%に抑うつ状態が合併するといわれています。当院で、入院中の循環器疾患患者さんに全例調査を行ったところ、約22%の方に中等度以上の抑うつ傾向があることがわかりました。

特に冠動脈疾患とうつ病の間には強い関連性があり、抑うつ傾向が多い理由としては、心拍変動の低下や交感神経の過剰亢進などがあげられ、冠動脈疾患でのうつ病の発症率リスクは2.8倍、また、うつ病の方の冠動脈疾患の発症リスクは2.5倍になるという報告がなされています。

循環器疾患でうつ病を併発すると、循環器疾患の転帰が不良となることが知られています。たとえば、心筋梗塞では、うつ病との合併症による死亡率が2.3倍、うっ血性心不全で1.8倍、不安定狭心症で3.3倍、冠動脈バイパス術後では2.4倍になるという報告がなされています。

また、循環器疾患においては冠動脈疾患で薬剤溶出ステントの登場、また致死性不整脈に対する薬物療法やカテーテルアブレーションの進歩、また植え込み型除細動器や両心室ペースメーカーなどの登場により冠動脈疾患の再狭窄が抑えられ、心臓性突然死にいたるケースが少なくなっ

たことで、うつ病の治療をすることでのQOLの維持・改善は循環器疾患においても重要なテーマになってきています。そのため、循環器診療において、うつ病の早期発見・早期治療（専門医との連携等）への取り組みは喫緊の課題のひとつとして考えられています。

■ICD使用者における抑うつ状態

ICD（植え込み型除細動器）を使用している患者さんには、高い割合でうつ病や不安障害が出てくるといわれています。サムエル・F・シアーズ・ジュニア（米・イースト・カロリナ大学）等によるとICD使用患者の24～87%の患者さんにうつ病や不安障害がみられ、13～38%が臨床上困難な不安を抱えており、若年層では、ICDを埋め込まれたことを精神的に受け入れられないとともに、ICDのショック作動が多い人が、抑うつ傾向が多いとされています。

私たちが行った調査では、ICD使用患者の32%が抑うつ状態を有し、その後の2年間の調査期間を経ても、約75%の患者さんに、抑うつが持続していることがわかりました。

ICDを埋め込んだ時点では、ほとんどすべての患者さんは埋め込んだことで安心でき、ICDのショック作動がなければ、問題なく、元気に日常生活を送ることができます。しかし、ICDを埋め込んでから1年間で半数の人にショック作動が起きるといわれています。頻繁にショック作動が起きることによって、いつどこでショック作動が起こるかかわからないという恐怖から、外出できない、電車に乗れない、またPTSDに近い症状として、シャワー中にショック作動が起きたりすると、それ以後、シャワーを浴びることができないなどの例もあり、うつ病や不安障害を発症するケースが多くみられます。私も頻回作動のため入院した患者さんが、ショック作動に対する恐怖心のあまり、退院が困難な状態になったというケースに遭遇したことがあります。

そのため海外では、ICDを埋め込んだ患者さんがうつ病を発症した際、