

brief limited intermittent psychotic symptoms (BLIPS), which are apparent psychotic symptoms that spontaneously remit within 1 week; and trait- and state-risk groups, in which the patient has a family history of psychosis (psychosis in first-degree relatives) or manifests schizotypal personality disorder along with low functioning that is sustained for at least 1 month. The transition rate of ARMS to full-blown psychosis has been reported to be approximately 10–50%, and this rate is considered to be influenced by the follow-up interval, type of intervention, settings of the service system and characteristics of the samples.<sup>3,6</sup>

People with ARMS exhibit a variety of symptoms, including non-specific psychiatric symptoms and attenuated positive symptoms, and most of them are diagnosed with comorbid axis-I disorders.<sup>4,7</sup> Therefore, it is essential to use a specific instrument for accurate identification and elaborate assessment of ARMS individuals. The Comprehensive Assessment of At-Risk Mental States (CAARMS)<sup>8</sup> and the Structured Interview for Prodromal Syndromes<sup>9</sup> are the two major instruments that have been developed to meet this need.

The CAARMS, which was developed at the PACE clinic in Melbourne, is a semi-structured interview designed to measure a wide variety of symptoms. It is thought to be useful for identifying and assessing symptoms, including attenuated positive symptoms, negative symptoms, general psychopathologies, behavioural changes and Huber's basic symptoms in people with ARMS. The reliability and validity of this instrument were confirmed by Yung *et al.*,<sup>8</sup> who conducted joint interviews of 34 UHR individuals to assess the inter-rater reliability of the instrument. The predictive validity was examined by comparing the 6-month transition rates of the CAARMS-defined UHR group ( $n = 43$ ) and the non-UHR group ( $n = 107$ ). The discriminant validity was assessed by comparing the CAARMS scores of UHR individuals ( $n = 48$ ) and the control group ( $n = 48$ ), and the concurrent validity was examined by testing the accordance between the CAARMS-defined UHR criteria and the Brief Psychiatric Rating Scale (BPRS)/Comprehensive Assessment of Symptoms and History (CASH)-defined UHR criteria in 49 participants. The CAARMS has been adopted in many countries/regions outside Australia, including the UK,<sup>10</sup> Korea<sup>11</sup> and Hong Kong.<sup>12</sup> However, only the original version has been assessed for reliability and validity.<sup>8</sup>

We assessed the generalizability of CAARMS by examining its applicability in Japan – a country with cultural and medical systems different from those of the other countries where the concepts of ARMS

and early intervention service have already been developed. We developed the Japanese version of the CAARMS (CAARMS-J), applied the instrument for the assessment of the Japanese population and evaluated its reliability and validity. The inter-rater reliability was examined by using the data from joint interviews of 40 ARMS individuals who met the CAARMS-J-defined UHR criteria (UHR+). The construct validity was assessed by comparing the Positive and Negative Syndrome Scale (PANSS) subscale scores and the basic symptoms of the UHR+ group with those of the first-episode psychosis (FEP) and UHR– (individuals who did not meet the CAARMS-J-defined UHR criteria) groups. The concurrent validity was examined by assessing the correlations of the positive and negative symptoms scores between CAARMS-J and PANSS. The predictive validity was assessed on the basis of the 12-month transition rate and the antipsychotics prescription rate in 28 UHR+ individuals.

## METHOD

### Participants

The participants were recruited from the Sendai at-risk mental state and first episode (SAFE) clinic at the Department of Psychiatry, Tohoku University Hospital; this clinic is an outpatient clinic for people with ARMS. The individuals who fulfilled the following inclusion criteria were defined as ARMS cases in this study: (i) those aged between 14 and 35 years; (ii) those seeking psychiatric help; and (iii) those fulfilling the UHR criteria defined by CAARMS-J. The exclusion criteria were: (i) a history of psychotic episodes, or a history of manic episodes that fulfilled the diagnostic criteria of bipolar I disorder specified in the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision (DSM-IV-TR) (bipolar I disorder being often as severe as psychotic disorders); (ii) history of treatment with antipsychotics; (iii) serious risk of suicide or violence due to a personality disorder; (iv) current substance dependence; (v) known intellectual disability (IQ < 70); and (vi) neurological disorders, head injury or any other significant medical condition associated with psychiatric symptoms. The study was carried out with the authorization of the Ethics Committee of Tohoku University Graduate School of Medicine and Tohoku University Hospital, and all the participants gave their written informed consent.

### Instruments

The CAARMS instrument encompasses different aspects of psychopathology and functioning in

TABLE 1. Demographic variables, and the scores of GAF, the PANSS and the CAARMS-J in three diagnostic groupst

	ARMS (n = 31)	FEP (n = 10)	Others (n = 20)	Test statistic	P	Post hoc test
Age Mean (SD)	20.3 (4.6)	19.3 (4.9)	20.8 (4.2)	$\chi^2 = 1.32$	0.516	–
Sex (M : F)	11:20	3:7	9:11	–	–	–
GAF Mean (SD)	47.7 (6.6)	36.4 (8.7)	49.6 (9.0)	$\chi^2 = 12.98$	0.002	others = ARMS > FEP
PANSS subscale scores						
Positive symptoms	15.5 (3.8)	18.5 (3.8)	10.8 (2.5)	$\chi^2 = 25.55$	<0.001	FEP = ARMS > others
Negative symptoms	14.5 (4.6)	19.0 (3.2)	13.8 (4.4)	$\chi^2 = 10.53$	0.005	FEP > ARMS = others
General psychopathology	38.8 (9.2)	37.5 (7.3)	30.8 (5.1)	$\chi^2 = 11.89$	0.003	FEP = ARMS > others
CAARMS-J						
Positive symptoms						
Thought content	3.8 (1.3)	4.9 (1.1)	1.3 (0.8)	$\chi^2 = 37.56$	<0.001	FEP = ARMS > others
Perceptual abnormalities	2.8 (1.7)	4.8 (1.5)	1.2 (1.0)	$\chi^2 = 24.80$	<0.001	FEP > ARMS > others
Disorganized speech	2.2 (1.2)	3.3 (1.3)	1.1 (1.0)	$\chi^2 = 18.64$	<0.001	FEP = ARMS > others
Huber's basic symptoms						
Subjective experience of cognitive change	2.7 (1.3)	3.5 (0.5)	2.0 (0.8)	$\chi^2 = 14.80$	0.001	FEP > others
Subjective complaints of impaired motor functioning	1.0 (1.2)	1.0 (1.2)	0.4 (0.7)	$\chi^2 = 5.33$	0.070	–
Subjective complaints of impaired bodily sensation	1.2 (1.7)	1.9 (2.1)	0.1 (0.4)	$\chi^2 = 11.40$	0.003	FEP = ARMS > others
Subjective complaints of impaired autonomic functioning	2.8 (1.0)	2.1 (1.7)	2.5 (1.1)	$\chi^2 = 2.29$	0.318	–
Subjective emotional disturbance	2.4 (1.1)	2.2 (1.4)	1.9 (1.3)	$\chi^2 = 1.53$	0.464	–
Avolition/apathy	3.0 (1.3)	3.1 (1.5)	2.6 (1.3)	$\chi^2 = 1.73$	0.422	–
Impaired tolerance to normal stress	3.1 (1.5)	3.2 (1.5)	2.4 (1.6)	$\chi^2 = 2.92$	0.232	–

†Data are given as mean (standard deviation (SD)) except where indicated otherwise.

GAF, The Global Assessment of Functioning; PANSS, The Positive and Negative Syndrome Scale; CAARMS-J, The Japanese version of the Comprehensive Assessment of At-Risk Mental States; ARMS, At-risk mental state group; FEP, First episode of psychosis group; Others, Other disorder group.

order to enable comprehensive assessment of individuals with ARMS. The CAARMS contains seven categories consisting of 28 subscales,<sup>8</sup> including some of Huber's basic symptoms<sup>13,14</sup> (Table 1). Each subscale is rated in terms of the dimensions of intensity (0–6) and frequency/duration (0–6). The positive symptoms category is used to determine the UHR criteria. The threshold of psychotic disorder is defined by operationalized clear-cut levels of positive symptoms occurring for at least 1 week, either on a daily basis or for more than three times a week with each symptom continuing for more than 1 hour on each occasion, according to the psychosis criteria defined by CAARMS-J.

The CAARMS was translated into Japanese by two Japanese psychiatrists (KM and TM) after obtaining permission from the original authors. As some colloquial English phrases were difficult to translate, we carefully selected words and phrases so that the translation would be in natural Japanese. This Japanese version of the CAARMS (the CAARMS-J instrument is available from the second author upon request) was back translated into English by professional translators who had not perused the original English text. The results of the back-translation were

examined and judged as satisfactory by a staff member of PACE who was familiar with the usage of the CAARMS.

The PANSS<sup>15</sup> is a 30-item scale designed to include three subscales for different types of symptoms: positive syndrome, negative syndrome and general psychopathology. The inter-rater reliability and the criterion-related and construct validities of PANSS were evaluated by Kay *et al.*,<sup>15</sup> and the inter-rater reliability and internal consistency of the Japanese version have been evaluated by Igarashi *et al.*<sup>16</sup>

## Procedures

### Inter-rater reliability

The inter-rater reliability of CAARMS-J was examined by using the data from consecutive joint interviews of 40 UHR+ individuals (10 males and 30 females; mean age  $\pm$  standard deviation (SD), 20.0  $\pm$  4.5 years) at intake. Initially, three psychiatrists trained each other on the usage of CAARMS-J, with help from the CAARMS training DVD. Preliminary administration of the instrument to suspected ARMS individuals was conducted before the study.

Two of the three raters were paired for each interview. We also assessed the inter-rater agreement for the UHR criteria.

### Construct validity

Sixty-one individuals (23 males and 38 females; age, 14–35 years; mean age  $\pm$  SD,  $20.3 \pm 4.5$  years) who consecutively attended an intake interview at the SAFE clinic participated in this study. All the participants were interviewed using CAARMS-J and PANSS. We used CAARMS-J to determine whether these individuals met the UHR criteria, and the axis-I diagnosis was made according to DSM-IV-TR on the basis of the agreement between two trained psychiatrists (KM and TM). After the interview, the participants were divided into three groups on the basis of the UHR criteria assessment: UHR+ group, FEP group and UHR– group (Table 1). The FEP group consisted of patients with schizophrenia ( $n = 2$ ), schizophreniform disorder ( $n = 2$ ), brief psychotic disorder ( $n = 3$ ) and psychotic disorder not otherwise specified ( $n = 3$ ). The UHR– group consisted of individuals who visited the SAFE clinic for risk assessment but did not meet the criteria of UHR or psychosis. They were diagnosed with anxiety disorders ( $n = 10$ ), depressive disorders ( $n = 6$ ), adjustment disorders ( $n = 4$ ), somatoform disorders ( $n = 2$ ) and no axis-I disorders ( $n = 1$ ); there were three individuals with dual diagnosis.

We assessed the construct validity of CAARMS-J by determining the presence of the characteristic features of ARMS in the CAARMS-J-defined ARMS individuals. We compared the UHR+, FEP and UHR– groups in terms of the PANSS positive-, negative- and general psychopathology-symptoms subscale scores and Huber's basic symptoms measured by CAARMS-J. We hypothesized that the positive-symptoms scores of the UHR+ group would be intermediate between those of the FEP and UHR– groups. Further, we predicted that the scores of some of Huber's basic symptoms in the UHR+ and FEP groups would be higher than those in the UHR– group, because the basic symptoms are self-experienced deficit symptoms which are thought to be observed through the entire course of schizophrenia, including the prodromal state.<sup>13</sup> It has also been reported that some of the basic symptoms predict the onset of psychosis.<sup>17</sup>

### Concurrent validity

The abovementioned 61 individuals participated in this study. The concurrent validity of CAARMS-J for evaluating psychotic symptoms was tested by

examining the correlations between the positive symptoms of CAARMS-J and the corresponding scales of PANSS. We verified the ability of CAARMS-J to measure negative symptoms by examining the correlation between the emotional disturbances and negative-symptoms category scores of CAARMS and the negative-symptoms subscale scores of PANSS.

### Predictive validity

The predictive validity of the CAARMS-J-defined UHR criteria was tested by consecutively identifying young people with ARMS according to the CAARMS-J-defined UHR criteria. Twenty-eight individuals with ARMS were followed up at the SAFE clinic. Twenty-three individuals met the APS criteria, one individual met the risk-factor criteria, three individuals met the APS and risk-factor criteria, and one individual met the APS and BLIPS criteria. The participants were treated by one of the three psychiatrists according to the treatment guidelines of the SAFE clinic. A summary of the guidelines is as follows. Eclectic psychological intervention combining supportive therapy and cognitive therapy was provided to all the participants. The prescription of antipsychotics was avoided unless the individuals (i) had an imminent risk of suicide or severe violence; (ii) were overwhelmed by psychotic symptoms; (iii) were rapidly deteriorating; or (iv) did not respond to any other treatment. Low-dose atypical antipsychotics were used, if necessary. Selective serotonin reuptake inhibitor or benzodiazepines were used to treat depression, anxiety and insomnia. The participants were usually followed up weekly or after every 2 weeks, in accordance with their clinical needs. We calculated the rate of transition to psychosis at 12 months and the rate of prescription of antipsychotic medication during the 12-month follow-up period. Psychosis was defined according to the CAARMS-J criteria. We predicted that the transition rate at 12 months would be comparable to that in other studies in which putatively effective treatments were provided.

### Data analysis

All statistical analyses were performed using the Statistical Package for Social Sciences (SPSS) 16.0 J for Windows (SPSS; Chicago, IL, USA). Intraclass correlations (ICCs) were calculated to assess inter-rater reliability, and the kappa coefficient was used to evaluate the inter-rater agreement on the diagnosis. Statistical comparisons across the three groups were examined by using the Kruskal–Wallis test, and post hoc comparisons were conducted by using the

Mann–Whitney *U* test with Bonferroni correction; the application of Bonferroni correction was found to reduce the level of significance from  $P < 0.05$  to  $P < 0.017$ . Spearman correlations were adopted to determine the correlation between the PANSS and CAARMS-J scores.

## RESULTS

### Inter-rater reliability of the CAARMS-J

The ICC coefficients of the seven categories and the three positive-symptoms subscales of CAARMS-J are shown in Table 2. We found very good to excellent agreement in all the categories and positive-symptoms subscales. The kappa coefficient for the agreement on the UHR criteria between the three raters was 0.82 ( $P < 0.001$ ).

### Construct validity

The PANSS positive-symptoms subscale scores were different among the three groups (Table 1). The PANSS positive-symptoms subscale scores of the UHR+ group were significantly higher than those of the UHR– group ( $P < 0.001$ ). The positive symptoms were more severe in the FEP group than in the UHR+ group, but the differences were not significant ( $P = 0.033$ ).

There were significant differences among the three groups in the PANSS negative-symptoms subscale scores and the PANSS general psychopathology subscale scores. The PANSS negative-symptoms subscale scores of the FEP group were significantly higher than those in the UHR+ ( $P = 0.002$ ) and the UHR– ( $P = 0.002$ ) groups; however, there was no

difference between the scores of the UHR+ and the UHR– groups ( $P = 0.698$ ). The PANSS general psychopathology scores for the UHR+ and FEP groups were significantly higher than those for the UHR– group ( $P = 0.001$  and  $P = 0.015$ , respectively), although there was no significant difference between the scores of the UHR+ and FEP groups ( $P = 0.879$ ).

In the assessment of Huber's basic symptoms, two of the seven subscales adopted in CAARMS (i.e. the subscales relating to subjective experience of cognitive change and impaired bodily sensation) showed a significant difference among the three groups (Table 1). The score for subjectively experienced cognitive change in the FEP group was significantly higher than that in the UHR– group ( $P < 0.001$ ). The individuals in the UHR+ group experienced subjectively higher cognitive change than those in the UHR– group ( $P = 0.030$ ), and the patients in the FEP group experienced subjectively higher cognitive change than those in the UHR+ group ( $P = 0.039$ ); however, the differences were not significant. The individuals in the FEP and UHR+ groups experienced higher impairment of body sensations than those in the UHR– group ( $P = 0.013$  and  $P = 0.004$ , respectively). There were no significant differences between the groups in the assessment of the other five Huber's basic symptoms.

### Concurrent validity

Table 3 shows the results of the Spearman correlation coefficient analysis between the CAARMS-J and PANSS subscales. Each subscale of the positive symptom scale of CAARMS-J correlated with the corresponding positive symptoms subscale of PANSS. Moreover, the emotional disturbance and negative symptoms category scores of CAARMS-J correlated with the negative symptom subscale score of PANSS.

### Predictive validity

Five of the 28 participants did not complete the 12-month follow-up period. Four of these participants moved out of the clinic catchment area and we ascertained the absence of psychosis in two participants by telephone interview; however, we could not complete the follow-up for the other two participants. The fifth participant stopped visiting our clinic at 4 months, and he could not be contacted.

After 12 months of follow-up, 3 of the 28 participants (10.7%) had transitioned to psychosis, and all three had been prescribed antipsychotics during the follow-up period; the prescription periods for the

TABLE 2. Intra-class correlation coefficients (ICCs) of eight main subscales of the CAARMS-J ( $n = 40$ )

CAARMS-J subscale	ICC
Positive symptoms	0.94
Disorder of thought content	0.91
Perceptual abnormalities	0.97
Conceptual disorganization	0.87
Cognitive change concentration/attention	0.76
Emotional disturbance	0.74
Negative symptoms	0.87
Behavioural change	0.76
Motor/physical changes	0.84
General psychopathology	0.92
Overall	0.92

CAARMS-J, The Japanese version of the Comprehensive Assessment of At-Risk Mental States.

TABLE 3. Spearman correlations of the CAARMS-J scores with PANSS scores ( $n = 61$ )

CAARMS	PANSS	$r$ (95% CI)
Positive symptoms	Positive symptoms	0.72* (0.57–0.82)
Thought content	delusion	0.85* (0.76–0.91)
Perceptual abnormalities	hallucinatory behaviour	0.90* (0.84–0.94)
Disorganized speech	conceptual disorganization	0.73* (0.58–0.83)
Emotional disturbance	Negative symptoms	0.64* (0.47–0.77)
Negative symptoms	Negative symptoms	0.53* (0.32–0.69)

\* $P < 0.01$ .

CAARMS-J, The Japanese version of the Comprehensive Assessment of At-Risk Mental States; CI, confidence interval; PANSS, The Positive and Negative Syndrome Scale.

three participants were 2, 10 and 22 weeks before the onset of psychosis, respectively. Antipsychotics were prescribed to 11 (39.2%) participants during the follow-up period. The average prescription period in the eight participants that did not progress to psychosis was  $20.4 \pm 18.5$  weeks (range: 2–48 weeks); three of these participants were still being prescribed antipsychotics at 12 months. One participant developed psychosis at 13 months. This participant had fulfilled the criteria for APS and BLIPS at intake, and she had been refusing to take the prescribed antipsychotics.

## DISCUSSION

This is the first study on the application of CAARMS and UHR criteria to the Japanese population and on the reliability and validity testing of CAARMS-J. The results indicate that CAARMS-J is a reliable and valid instrument for evaluating ARMS in the Japanese population. CAARMS and the concept of ARMS seem to exhibit generalizability across different cultures.

The ICC of each subscale of CAARMS-J showed good to excellent reliability, which was comparable to that reported by Yung *et al.*<sup>8</sup> The result demonstrated that CAARMS-J could be used for the reliable assessment of the comprehensive symptoms of ARMS. The inter-rater reliability of the UHR criteria defined by CAARMS-J was also confirmed to be satisfactory, as observed in the original study.<sup>8</sup>

The positive-symptoms subscale scores of the UHR+ group were intermediate between those of the FEP and UHR- groups. A similar pattern was observed in a study showing the intermediate severity of positive symptoms measured by the Scale of Prodromal Symptoms in ARMS individuals.<sup>18</sup> Miller *et al.* reported that the PANSS positive-symptoms subscales in the ARMS individuals were less severe than those in untreated patients with first-episode schizophrenia, but comparable to those in treated

first-episode patients.<sup>19</sup> Most of the psychotic patients in our study were referred for apparently mild positive symptoms, and five of them already had been treated with antipsychotics; therefore, these patients were relatively stable. This could have been the reason for the absence of significant differences between the positive symptoms in the FEP and UHR+ groups.

The FEP group was determined on the basis of the positive symptom scores of CAARMS-J; however, the severity of the PANSS negative-symptoms subscales in the FEP group was significantly more than that in the UHR- group. It has been reported that the severity of negative symptoms in first-episode patients is usually greater than that in ARMS individuals.<sup>20–22</sup> The ARMS individuals who develop psychosis may exhibit more severe negative symptoms.<sup>8</sup>

The UHR+ and FEP groups had a higher general psychopathology score than the UHR- group. However, there was no significant difference between the UHR+ and FEP groups. This finding proves that the ARMS individuals in our study were not just a group of individuals undergoing incidental psychotic-like experiences with a relatively low risk of developing psychosis, but they were suffering from a general psychopathology that was as severe as that found in the FEP patients. Furthermore, the majority of ARMS individuals in our study were referred from psychiatrists who may have recognized the patients' risk of developing psychosis and their needs for specific psychiatric treatment.

The CAARMS contains several items that assess Huber's basic symptoms, which are thought to be prominent in ARMS individuals and patients with schizophrenia.<sup>17,23</sup> In the present study, the severity of two of the seven basic symptoms – subjective experience of cognitive change and subjective complaints of impaired bodily sensation – were different among the three groups; the scores of these symptoms in the UHR+ and FEP groups were higher than those in the UHR- group. These findings may be

indicative of the sensitivity of the cognitive change and impaired body sensation items in signalling the imminent risk of psychosis, and the indistinguishability of the other five items from non-specific psychiatric symptoms. Specialized instruments for measuring basic symptoms in ARMS individuals such as Schizophrenia Proneness Instrument, Adult-version,<sup>24</sup> could prove useful for reinforcement of the UHR criteria.

We expected that the positive and negative symptoms measured by CAARMS-J would correlate with those assessed by PANSS. The present results demonstrated that this expectation was justified. The present study demonstrated that CAARMS-J has good concurrent validity with PANSS in measuring the positive and negative symptoms of ARMS.

The methodological limitations of our study must be considered when comparing the results after the 12-month follow-up in our UHR-positive group with those of other studies. In the present study, we provided interventions that were expected to be effective for ARMS individuals, because optimal treatment for the patients was ethically required in our clinical setting. In addition, our interventions were not controlled and not uniformly delivered. However, in light of these limitations, the overview of transition rates in other studies in which active interventions were implemented may provide interesting insights. McGorry *et al.*<sup>25</sup> performed a randomized control study in which they compared the transition rate of ARMS individuals who were treated with specific prevention intervention (SPI), which combined cognitive-behavioural therapy and low-dose antipsychotic medication with that of ARMS individuals who were treated with need-based intervention (NBI). The transition rate of the SPI group was 10% at the end of the treatment phase and 19% at the 12-month follow-up; however, the transition rate of the NBI group was 36% at the end of the 6-month treatment phase and the 12-month follow-up. Morrison *et al.* conducted a randomized control study and reported that the transition rate at the 12-month follow-up was 6% for the ARMS individuals who received cognitive therapy for 6 months and 26% for those who did not receive the therapy.<sup>26</sup> In a North American longitudinal study that was conducted across eight clinical research centres, 291 subjects were longitudinally followed up with treatment that was administered according to the clinical judgment of the treating physicians, and the transition rate was  $12.7 \pm 1.9\%$  at 6 months,  $21.7 \pm 2.5\%$  at 12 months and  $32.6 \pm 3.3\%$  at 24 months.<sup>27</sup> Considering these results, it can be assumed that CAARMS-J can reliably detect ARMS individuals.

The antipsychotic prescription rate in our study (39.2%) was almost similar to that in the abovementioned North American longitudinal study (35.1%).<sup>27</sup> In our study, 8 of the 11 participants who received antipsychotic medications did not progress to psychosis during the follow-up period; however, the other three participants developed psychosis in spite of receiving the treatment. The antipsychotic medication could have delayed or avoided the conversion to psychosis in some of the cases that did not progress to psychosis;<sup>25,28</sup> however, the use of this treatment method in these circumstances is still open to debate.<sup>29</sup> Out of the 20 individuals who completed the follow-up period without developing psychosis, only three participants were being prescribed antipsychotics at 12 months, which implies that the continuous prescription of antipsychotics to ARMS individuals is not always necessary. Considering the active treatment provided to the ARMS individuals and the relatively short period of follow-up in this study, it can be assumed that more than 10.7% participants may actually develop psychosis. In fact, one participant progressed to psychosis after the 12-month follow-up period (onset at 13 months) despite undergoing continuous treatment, which implies that at least 14.3% of the participants in our UHR+ group were at risk of developing psychosis after a longer follow-up period. However, the transition rate in our study seems to be low, and it supports the recent advocacy of more benign forms of treatment for ARMS individuals.<sup>29</sup>

There were certain other limitations in this study. Firstly, the results were obtained by a small group of raters who had considerable clinical experience of assessing individuals with prodromal symptoms and were familiar with CAARMS-J. The generalizability of the results should be studied in the future. Secondly, the sample size was small and the number of female participants was almost double that of the male participants. This might be attributed to the fact that more female individuals visited our ARMS clinic. Finally, first-episode psychosis patients were not represented in this diagnostic population because they visited our clinic for suspected diagnosis of prodrome. This fact indicates that our ARMS clinic can also act as a gateway in the identification of FEP patients. The development of ARMS clinics is proving to be of great benefit for the advancement of early intervention in psychosis.

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Regular Article

## Psychometric properties of the Japanese version of the Beck Cognitive Insight Scale: Relation of cognitive insight to clinical insight

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**Aim:** Insight in schizophrenia is considered to have a multidimensional construct, and cognitive insight is thought to be an important dimension of insight: an ability to evaluate and correct one's own distorted beliefs and misinterpretations. The Beck Cognitive Insight Scale (BCIS) was developed to measure cognitive insight, and studies have shown that cognitive insight is associated with several clinical features in schizophrenia. The aim of the present study was to develop a Japanese version of the BCIS (BCIS-J) and assess the psychometric properties of this instrument.

**Methods:** The BCIS-J was completed by university students ( $n = 183$ ) and patients with schizophrenia ( $n = 30$ ). The Japanese version of the Schedule for the Assessment of Insight was used to measure clinical insight in patients with schizophrenia, and its association with the BCIS-J was investigated.

**Results:** Factor analysis in the university students indicated that the BCIS-J was composed of two factors, self-reflectiveness and self-certainty, as was seen in the original BCIS. The relation between the specific dimensions of clinical insight and each component of the BCIS-J in patients with schizophrenia indicated that overconfidence in their belief or judgment may be involved in their attitude to treatment and openness to feedback, and objectivity might be essential to attribute one's symptoms as part of mental illness.

**Conclusions:** The BCIS-J is a reliable and valid instrument to measure cognitive aspects of insight and appears to complement clinical insight scales.

**Key words:** cognitive insight, schizophrenia, self-reflectiveness, self-certainty.

LACK OF INSIGHT is considered to be one of most important features in the pathogenesis, diagnosis, and treatment of schizophrenia. A contemporary model of insight regards it as a multidimensional

continuum rather than a unitary 'all or none' phenomenon.<sup>1,2</sup> According to this model, researchers investigate clinical aspects of insight (clinical insight<sup>3</sup>), such as awareness of mental disorder, recognition of need for treatment, and ability to relabel unusual mental events as pathological.<sup>2,4-6</sup>

Beck *et al.* recently proposed another aspect of insight from the cognitive point of view, namely, cognitive insight.<sup>3</sup> Cognitive insight is conceptualized as an ability to evaluate and correct one's own distorted beliefs and misinterpretations, and a higher

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level of cognitive process is hypothesized to be involved in it. To measure this aspect of insight, the Beck Cognitive Insight Scale (BCIS) was developed.<sup>3</sup> The initial study by Beck *et al.* found that the BCIS is composed of two components: self-reflectiveness and self-certainty.<sup>3</sup> The former includes items measuring objectivity, reflectiveness, and openness to feedback, and the latter measures certainty about one's own beliefs or judgment. A composite index score, an estimated measure of overall cognitive insight, is calculated by subtracting the score for the self-certainty subscale from the score for the self-reflectiveness subscale.

Reliability and validity of the instruments have been shown in a mixed group of inpatients with psychosis and depression,<sup>3</sup> a group of middle-aged and older outpatients with schizophrenia,<sup>7</sup> and a group of patients with bipolar disorder.<sup>8</sup> The BCIS was also applied to the normal population.<sup>9,10</sup> Internal consistency of the BCIS was considered to be similar between clinical and non-clinical samples,<sup>8,10</sup> but factor loading or factor structure of the BCIS in the normal population has not been reported except in a poster presentation by Warman *et al.* (unpubl. data, 2004).

Overall cognitive insight indicated by the composite index scale of the BCIS in patients with schizophrenia has been shown to be correlated with clinical insight measured by the Scale to Assess Unawareness of Mental Disorder (SUMD)<sup>3,11</sup> and the Birchwood Insight Scale (IS).<sup>7</sup> The association, however, between the individual items of the clinical insight scales and the subscales of the BCIS has not been fully explored. Beck *et al.* observed a correlation between the SUMD awareness of delusion and self-reflectiveness, but no other correlation was found except for the relation between the SUMD awareness of mental disorder and the composite index.<sup>3</sup> Pedrelli *et al.* reported a correlation between the self-reflectiveness and the relabel subscale and the total score from the IS.<sup>7</sup>

Clinical insight is known to be associated with depression in patients with psychosis,<sup>12,13</sup> that is, patients become more depressed as insight increases. It is not clear, however, whether this is true for cognitive insight. One study found a correlation between depression measured by the Beck Depression Inventory-II (BDI-II) and cognitive insight in patients with schizophrenia or schizoaffective disorder,<sup>10</sup> but another study did not find such a correlation.<sup>3</sup> Pedrelli *et al.* found no association between depression measured by the Hamilton Rating Scale for

Depression in middle-aged and older patients with schizophrenia and schizoaffective disorder.<sup>7</sup>

In the present study we developed the Japanese version of the BCIS (BCIS-J) and investigated psychometric properties of this instrument. The BCIS-J was applied to healthy university students to determine the factor structure of the BCIS-J and to evaluate the reliability of the instrument in a normal population sample. We predicted that the factor structure of the BCIS-J in the normal sample is similar to that of the original BCIS. We then evaluated the BCIS-J and the Japanese version of the Schedule for the Assessment of Insight (SAI-J)<sup>14</sup> in patients with schizophrenia to determine the association between clinical and cognitive insight. We were particularly interested in the association between each component of the BCIS-J and the three subscales of the SAI-J, that is, adherence with treatment, awareness of illness, and relabeling of psychotic phenomena. We also investigated the relationship between the cognitive insight and psychosocial variables in patients with schizophrenia.

## METHODS

### Japanese version of the Beck Cognitive Insight Scale

The BCIS is a self-report instrument consisting of 15 items rated on a 4-point scale (0, do not agree at all; to 3, agree completely). With the original authors' permission, the BCIS was first translated into Japanese by one of the authors (A.K.). This Japanese version of the BCIS was back-translated into English by a bilingual psychologist who had not previously seen the original English text. The results of the back-translation were then examined and judged satisfactory by a native-English-speaking psychologist who was an expert in cognitive psychology.

### Other instruments

The SAI-J was translated from the original SAI,<sup>2</sup> and the reliability and validity of the SAI-J has been confirmed by Sakai *et al.*<sup>14</sup> The SAI is a semi-structured clinical interview designed to measure clinical insight, and it consists of seven items constituting three subscales: (i) adherence to treatment; (ii) awareness of illness; and (iii) relabeling of psychotic phenomena.<sup>2</sup> The Positive and Negative Syndrome Scale (PANSS) is a 30-item scale designed to include

three subscales for different types of symptoms: positive symptoms, negative symptoms, and general psychopathology.<sup>15</sup> Yamada *et al.* translated the PANSS Rating Manual into Japanese and applied this scale in Japan.<sup>16</sup> The BDI-II is a 21-item self-report instrument developed to measure the severity of depression in adults and adolescents.<sup>17</sup> The reliability and validity of the Japanese version of the BDI-II has been established by Kojima *et al.*<sup>18</sup>

## Participants

One hundred and eighty-three university students (104 men and 79 women with a mean age of  $18.9 \pm 1.2$  years) were recruited at Tohoku University. Participants were asked as part of the questionnaire if they had ever been diagnosed with a psychiatric disorder. Participants who reported a history of psychiatric disorder diagnosis were excluded from the university student sample.

Thirty patients with schizophrenia or schizophreniform disorder (15 men and 15 women) were recruited from Tohoku University Hospital (Table 1). All of the diagnoses were made according to the DSM-IV-TR criteria<sup>19</sup> by a trained psychiatrist (K.M.) on the basis of all available information. All patients were clinically judged to be stable enough to undergo the assessment. All participants provided written informed consent and voluntarily agreed to participate. The research was approved by the Ethics Committee of Tohoku University Graduate School of Medicine and Tohoku University Hospital.

**Table 1.** Subject characteristics

Variables	Mean $\pm$ SD
Age (years)	26.73 $\pm$ 6.09
Education (years)	12.60 $\pm$ 2.25
Duration of illness (months)	46.13 $\pm$ 58.90
Antipsychotic drug (mg/day, chlorpromazine equivalence)	655.60 $\pm$ 489.01
BDI-II total	20.50 $\pm$ 13.09
SAI-J total	8.93 $\pm$ 3.27
PANSS positive	15.43 $\pm$ 5.52
PANSS negative	18.07 $\pm$ 6.00
PANSS general	36.97 $\pm$ 6.99
PANSS total	70.47 $\pm$ 16.18

BDI-II, Beck Depression Inventory-II; PANSS, Positive and Negative Syndrome Scale; SAI-J, Japanese version of the Schedule for the Assessment of Insight.

## Procedure

### University student sample

After the administration of the BCIS-J to the university student sample, factor analysis was conducted to assess the factor structure of the BCIS-J. Reliability of the BCIS-J was tested using coefficient alpha and the test-retest method. To examine the test-retest reliability of the BCIS-J, 52 subjects (27 men, 25 women with a mean age of  $18.9 \pm 1.8$  years) from the original sample were retested 3 weeks after the initial test. The correlations among self-reflectiveness, self-certainty and composite index were investigated in order to evaluate the internal relationships in the BCIS-J.

### Schizophrenia sample

The PANSS and the SAI-J were administered by a senior psychiatrist (K.M.) and a research psychologist (T.U.) with extensive training in administration of these measures, and the rating was determined by consensus of the two. The BCIS-J and the BDI-II then were completed by the participants immediately after the assessment with the PANSS and the SAI-J.

Correlation analysis with 95% confidence interval (95%CI) was conducted to determine the relation of the BCIS-J scores and the total and individual subscale scores of the SAI-J, BDI-II, the positive and negative syndrome scores and the insight subscales of the PANSS, and other demographic variables. The *t*-test was used to estimate the effects of sex on cognitive insight.

## Statistical analysis

All statistical analyses were performed using the Japanese version of SPSS 14.0 for Windows (SPSS, Chicago, IL, USA), with the significance level set at  $P < 0.05$  (two-tailed test).

## RESULTS

### University student sample

#### Factor analysis and reliability

The varimax-rotated principal factor method for the 15 BCIS-J items is shown in Table 2. From the results of factor analysis, the two-factor solution was determined by scree plot inspection and was found to be interpretable.

Table 2. Varimax-rotated principal factor method for the BCIS-J

Item	I	II	h <sup>2</sup>
10 When people disagree with me, they are generally wrong.	0.71	0.07	0.51
2 My interpretations of my experiences are definitely right.	0.70	-0.11	0.50
13 I can trust my own judgment at all times.	0.69	-0.03	0.48
9 I know better than anyone else what my problems are.	0.55	-0.03	0.31
11 I cannot trust other people's opinion about my experiences.	0.53	0.08	0.29
7 If something feels right, it means that it is right.	0.52	-0.07	0.28
8 Even though I feel strongly that I am right, I could be wrong.	-0.24	0.62	0.44
6 Some of the ideas I was certain were true turned out to be false.	-0.18	0.59	0.38
5 Some of my experiences that have seemed very real may have been due to my imagination.	0.06	0.47	0.23
4 I have jumped to conclusions too fast.	0.01	0.45	0.21
12 If somebody points out that my beliefs are wrong, I am willing to consider it.	-0.27	0.44	0.26
1 At times, I have misunderstood other people's attitudes towards me.	-0.01	0.44	0.19
3 Other people can understand the cause of my unusual experiences better than I can.	0.04	0.34	0.12
14 There is often more than one possible explanation for why people act the way they do.	-0.01	0.31	0.10
15 My unusual experiences may be due to my being extremely upset or stressed.	0.08	0.20	0.05
%Total	16.68	12.16	28.83
%Common	58	42	100

BCIS-J, Japanese version of the Beck Cognitive Insight Scale.

Factor I consisted of six items, which had salient loadings (>0.30): 2 (definitely right), 7 (feels right is right), 9 (know problems), 10 (people are wrong), 11 (cannot trust opinion), and 13 (trust own judgment). All of these items address overconfidence about beliefs or judgments and comprise 'self-certainty' component as in the original BCIS. Factor II contained items 1 (have misunderstood), 3 (others more objective), 4 (jumped to conclusions), 5 (due to imagination), 6 (ideas were false), 8 (could be wrong), 12 (willingness to consider), and 14 (possible explanation). Although only item 15 (due to stress) did not have a salient loading (0.20), we nevertheless included this item in the factor II in accordance with the original BCIS.<sup>3</sup> Factor II therefore consisted of the nine statements that were termed 'self-reflectiveness' and which included items related to openness to feedback, recognition of having jumped to conclusions at times, and ability to acknowledge fallibility. These are the same nine items as those in the self-reflectiveness component of the original BCIS. The composite index was calculated by subtracting the self-certainty score from the self-reflectiveness score, as in the original BCIS study.<sup>3</sup> The mean of the self-reflectiveness, self-certainty, and composite index scores for the university students was  $11.53 \pm 3.47$ ,  $4.24 \pm 3.00$ , and  $7.30 \pm 4.70$ , respectively.

The internal consistencies of the self-certainty and self-reflectiveness scores were measured by calculating Cronbach alpha coefficients. The coefficient alphas of the self-certainty and self-reflectiveness scores were 0.78 and 0.67. The stability of the scale was established by using the test-retest method. The 3-week test-retest reliability of the self-reflectiveness, self-certainty, and composite index scores were acceptable (Table 3).

The self-reflectiveness and self-certainty scores were found to significantly correlate with the composite index ( $r = 0.77$ , 95%CI: 0.70–0.82,  $P < 0.01$ ;  $r = -0.68$ , 95%CI: -0.75 to -0.59,  $P < 0.01$ , respectively).

Table 3. Test-retest correlations of the BCIS-J

	Mean ( $\pm$ SD)		Reliability coefficient
	First	Second	ICC
Self-reflectiveness	11.85 $\pm$ 3.30	11.92 $\pm$ 3.37	0.86**
Self-certainty	4.27 $\pm$ 2.13	4.00 $\pm$ 2.13	0.79**
Composite index	7.58 $\pm$ 3.65	7.92 $\pm$ 4.21	0.82**

\*\* $P < 0.01$ .

BCIS-J, Japanese version of the Beck Cognitive Insight Scale; ICC, intra-class coefficient.

Table 4. Pearson correlations between cognitive and clinical insight in patients

	BCIS-J					
	Self-reflectiveness		Self-certainty		Composite-index	
	<i>r</i> (95%CI)	<i>P</i>	<i>r</i> (95%CI)	<i>P</i>	<i>r</i> (95%CI)	<i>P</i>
SAI-J						
Adherence to treatment	0.16 (–0.21–0.50)	0.39	–0.38 (–0.65–0.02)	0.04*	0.34 (–0.02–0.62)	0.07
Awareness of illness	0.43 (0.08–0.68)	0.02*	–0.30 (–0.60–0.07)	0.11	0.48 (0.14–0.72)	0.01**
Relabeling of psychotic phenomena	0.41 (0.06–0.67)	0.02*	0.12 (–0.25–0.46)	0.54	0.23 (–0.14–0.55)	0.23
Total score	0.52 (0.20–0.74)	0.00**	–0.22 (–0.54–0.15)	0.24	0.50 (0.17–0.73)	0.01**

\* $P < 0.05$ , \*\* $P < 0.01$ .

BCIS-J, Japanese version of the Beck Cognitive Insight Scale; CI, confidence interval; SAI-J, Japanese version of the Schedule for the Assessment of Insight.

No significant correlation was found between the self-reflectiveness and self-certainty scores.

#### Schizophrenia sample

The mean of the self-reflectiveness, self-certainty, and composite index scores for the patients with schizophrenia were  $12.37 \pm 4.08$ ,  $6.53 \pm 3.28$ , and  $5.83 \pm 5.74$ , respectively.

#### Relation of the BCIS-J to clinical insight

The self-reflectiveness and composite index scores were significantly correlated with the SAI-J total score (Table 4) and the insight subscale of the PANSS ( $r = -0.39$ , 95%CI:  $-0.66$  to  $-0.03$ ,  $P < 0.05$ ;  $r = -0.45$ , 95%CI:  $-0.70$  to  $-0.11$ ,  $P < 0.01$ , respectively).

The subscales of the SAI-J were significantly correlated with the indicated BCIS-J scores: the adherence to treatment subscale with self-certainty score, the awareness of illness subscale with the self-reflectiveness and composite index, and the relabeling of psychotic phenomena subscale with self-reflectiveness score (Table 4).

#### Correlations of the BCIS-J with psychosocial variables

The composite index score was significantly correlated with the BDI-II ( $r = 0.42$ , 95%CI:  $0.07$ – $0.67$ ,  $P < 0.05$ ). No significant correlation was found between the BCIS-J and the other symptom measures.

The self-reflectiveness and composite index scores were significantly correlated with age ( $r = -0.37$ , 95%CI:  $-0.64$  to  $-0.01$ ,  $P < 0.05$ ;  $r = -0.47$ , 95%CI:  $-0.71$  to  $-0.13$ ,  $P < 0.01$ , respectively), and the self-certainty score was significantly correlated with duration of illness ( $r = 0.46$ , 95%CI:  $0.12$ – $0.70$ ,  $P < 0.05$ ). No other effect was observed.

To remove the effect of age or duration of illness on cognitive insight scales, we conducted partial correlation analysis and found no noticeable difference between the result of the partial and the usual correlation analysis.

## DISCUSSION

In the present study we developed the BCIS-J and examined psychometric properties of the instrument in healthy university students and patients with schizophrenia.

Factor analysis of the BCIS-J in healthy volunteers showed that the BCIS-J was composed of two factors, self-reflectiveness and self-certainty, which was the same as that in the original BCIS determined by Beck *et al.* in a sample of inpatients with schizophrenia, schizoaffective disorder, or mood disorder.<sup>3</sup> The coefficient alpha of the self-reflectiveness scores was  $< 0.70$ , similar to that in the original study,<sup>3</sup> but this value is considered acceptable for the present research purpose given that the subscales are composed of fewer than 10 items.<sup>3</sup> The present findings are consistent with the previous study by Warman *et al.*, which confirmed that the basic factor structure and internal consistency of the BCIS was similar for

the normal population and the clinical sample (Warman *et al.*, unpubl. data, 2004). Recently Engh *et al.* also observed acceptable internal consistency of the BCIS in a Turkish normal sample.<sup>8</sup> The findings supported generalizability of the two-factor components of cognitive insight to the non-clinical healthy sample as well as to the clinical sample.<sup>7</sup> The test-retest reliability intra-class coefficients of the BCIS-J confirmed stability of cognitive insight in the normal population. The results in the university student sample indicate reliability of the BCIS-J.

Cognitive insight is considered as a cognitive process rather than an insight into illness itself, and the common cognitive process might be attributable to the cognitive insight between the non-clinical healthy sample and clinical sample. Warman and Martin, for example, demonstrated that university students who had no history of psychotic disorders but were more prone to delusions were overconfident in their judgment,<sup>9</sup> similar to the delusional patients with psychotic disorders.<sup>10</sup>

Overall cognitive insight measured by the composite index of the BCIS-J was significantly correlated with clinical insight as measured by the total score of the SAI-J and the insight subscale of the PANSS. This is compatible with studies that found a correlation between the composite index score of the BCIS and clinical insight measured by the total score of IS,<sup>7</sup> and the SUMD total sum of three global items.<sup>11</sup> Overall cognitive insight appears to assess different but related aspects of insight, and the BCIS-J appears to have convergent validity.

The relation between the different aspects of clinical insight and each component of cognitive insight was examined. The negative correlation between the self-certainty and the treatment subscale of the SAI-J in the present study suggests that patients who are overconfident in their judgment less clearly realize their need for treatment. Previous studies have shown that poor clinical insight is associated with non-adherence to treatment in patients with schizophrenia.<sup>20,21</sup> Overconfidence in belief or judgment may be involved in the attitude to treatment of patients with schizophrenia. Self-reflectiveness, however, was correlated with the awareness of illness and relabeling of psychotic phenomena subscales of the SAI-J. These results are consistent with some of the findings of previous studies that found a correlation of self-reflectiveness with the ability to relabel psychotic symptoms but not with the ability to accept mental illness.<sup>3,7</sup> Openness to feedback and objectivity might

be essential to attribute one's symptoms to mental illness. Self-reflectiveness as well as overall cognitive insight seem to be important in the awareness of mental disorder, as was found in both the present study and that by Beck *et al.*<sup>3</sup>

The previous study by Warman *et al.* observed a positive correlation between cognitive insight and depression in patients with schizophrenia,<sup>10</sup> whereas Beck *et al.* found such an association only in patients with major depression but not in patients with schizophrenia.<sup>3</sup> The present finding supports the former result, that is, cognitive insight appears to be correlated with depression in schizophrenia, as clinical insight is.<sup>12,13</sup>

A limitation of the present study was the small sample size. This precluded thorough investigation of factor structure and reliability of the BCIS-J in patients with schizophrenia. Future research should be done with a diverse and larger sample of patients to explore the additional psychometric properties of the BCIS-J.

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第 104 回日本精神神経学会総会

シンポジウム

## 精神病発症危険群への治療的介入：SAFE ころのリスク外来の試み

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## はじめに

統合失調症をはじめとした精神病性障害（ここでは精神病；psychosis とする）に将来発展するリスクが高い精神状態に対してアットリスク精神状態（At-Risk Mental State：ARMS）という概念で規定し、早期介入を行う試みが海外で展開されてきている<sup>1)5)</sup>。東北大学病院精神科 SAFE（Sendai At-risk mental state and First Episode）ころのリスク外来では、この ARMS を対象にした専門外来を実施しており、ARMS に対する治療的介入を試みている。本論では、ARMS に対する早期介入について概観し、我々の活動の一端を紹介したい。

## 1. ARMS の概念

ARMS の概念は、オーストラリア・メルボルンの PACE（Personal Assessment and Crisis Evaluation）クリニックで発展し、精神病に将来発展するリスクが高いと考えられる精神状態を呈する 3 つの群によって定義されている<sup>5,18)</sup>。これらは、①頻度の乏しいあるいは不完全な精神病症状を現す「閾値下精神病症状群」、②明らかな精神病症状を一過性にのみ経験する「短期間欠型精神病症状群」、③第一度近親者が精神病あるいは当事者が統合失調型パーソナリティ障害などの素因があり、その上 1 年間で GAF 得点が 30 % 低下するほどの機能低下をきたす「素因と状態のリスク群」あるいは「脆弱群」である。PACE クリニックでは、これら 3 群のいずれかの状態に

ある若者が精神症状と関連して何らかの助けを求めている（help-seeking）場合に、早期介入の対象者としている。この基準は、北米の PRIME（Prevention through Risk Identification and Management）やドイツの FETZ（Früherkennungs und Therapiezentrum）においても採用されているが、FETZ では、さらに特定の基底症状を示す群を ARMS に加えており、基底症状群と上記の③の群を ARMS の早期（早期初回前駆状態）とし、未分化なあるいは一過性の陽性症状が出現する上記の①と②は、ARMS の後期（後期初回前駆状態）として区別している<sup>1)</sup>。

## 2. ARMS に対する早期介入

ARMS の対象者は、精神病という観点から見れば、精神病にはまだ至っていないがその徴候を示しているハイリスク者である。一方で、微弱な陽性症状の他にも、抑うつ、不安、強迫、対人恐怖、不眠など様々な精神症状を呈しており、既に何らかの精神障害に罹患しているという面を併せもっていることがほとんどである。したがって、ARMS の介入には、①現在経験している症状の治療と問題の解決、②より重度の精神障害（精神病や統合失調症）の予防という、大きく 2 つの目的が存在することになる<sup>12)</sup>。この 2 つの目的を達成するための最適なアプローチを求め、海外ではいくつかの研究グループによって ARMS への介入研究が行われてきた。

薬物療法については、少量の新規抗精神病薬に

表1 抗精神病薬治療と認知行動療法のメリットとデメリット

抗精神病薬治療	認知行動療法
<p>メリット</p> <ul style="list-style-type: none"> <li>・ 閾値下の精神病症状に対する抗精神病作用</li> <li>・ 抗精神病薬のもつ非特異的な効果</li> <li>・ 再発予防と同様な効果の期待</li> <li>・ 病的過程から脳を保護する可能性</li> </ul> <p>デメリット</p> <ul style="list-style-type: none"> <li>・ 不快な副作用の可能性（短期的・長期的）</li> <li>・ 服薬遵守のばらつき</li> <li>・ ステイグマの可能性</li> <li>・ 成長中の脳への影響は不明</li> <li>・ 精神病に移行しない偽陽性症例への倫理的問題</li> </ul>	<p>メリット</p> <ul style="list-style-type: none"> <li>・ 侵襲性が小さい</li> <li>・ 利用者に好まれる場合が多い</li> <li>・ 不安障害、うつ病にも適用可</li> <li>・ 偽陽性例への倫理的問題が少ない</li> </ul> <p>デメリット</p> <ul style="list-style-type: none"> <li>・ 病状によっては、施行が困難</li> <li>・ 脳内の過程が存在した場合の効果の限界</li> <li>・ 顕在発症例への効果は限定的</li> <li>・ 実施可能な治療者の不足</li> <li>・ 医療経済的な裏づけが乏しい</li> </ul>

よる治療効果が期待されている。PACEにおける無作為対照試験<sup>14)</sup>では、1~2 mg のリスベリドンと認知行動療法（CBT）を組み合わせた治療を6ヶ月間行った群の精神病移行率（約10%）は、これを行わなかった群（約36%）と比較して低かった。さらに、6ヶ月の介入期間中のリスベリドンに対する服薬アドヒアランスが高かった者は、介入期間終了後の6ヶ月間においても精神病への移行率は低いままで経過した。この研究では、CBTも同時に行われているためリスベリドン単独の効果のみをみることはできないが、短期間の抗精神病薬の継続的服薬によって、服薬中止後も持続する予防効果が得られる可能性が示唆されている。PRIMEでは、オランザピン（5~15 mg）とプラセボが比較され<sup>15)</sup>、オランザピン投与群の精神病移行率（約16%）は、プラセボ投与群（約38%）と比較して低かったが、この差は統計学的には有意でなかった（ $p=0.08$ ）。一方、この研究では服薬中断者の割合がオランザピン群（約55%）とプラセボ群（約35%）の両群において高く、オランザピン群では体重増加（平均8.8 kg）と倦怠感の訴えが有意に高かった。抗精神病薬以外の薬物については、SSRIなどの抗うつ薬が効果的であると指摘されており<sup>4)</sup>、オメガ3脂肪酸によって精神病移行率が下がるという報告もなされている<sup>2)</sup>。

精神療法については、先に示したPACEの研究

究<sup>14)</sup>では、リスベリドンと組合せたCBTによる介入に効果があることが示されているが、CBTが治療効果にどの程度寄与しているかは、この研究では定かではない。マンチェスターのEDIE（Early Detection and Intervention Evaluation）では、6ヶ月間ベックのモデルなどに基づく認知療法<sup>9)</sup>を行った群と観察群とを比較したところ<sup>17)</sup>、インテイクから12ヶ月後の精神病移行率は認知療法群（約6%）が、観察群（約26%）よりも低かった。また、3年後の追跡調査<sup>16)</sup>では、精神病移行率は認知療法群（約20%）と観察群（約30%）との間に差は認めなかったが、抗精神病薬の服用率は認知療法群（14%）の方が観察群（約34%）よりも低かった。ドイツのFETZでは、先述した早期初回前駆状態に対しては、CBTを中心とした複合的な心理介入を行い、後期初回前駆状態に対しては、amisulprideを投与するというプロトコールで研究が行われている<sup>1)</sup>。

上述の通り、現在のところ海外では主に抗精神病薬と認知行動療法を用いた治療介入が研究されているが、実際の臨床サービスの現場では、ケースマネジメント、支持的精神療法、心理教育、家族介入を含めた複合的な心理社会的アプローチや症状に応じた薬物療法が実施されている<sup>11,12,18)</sup>。表1は、抗精神病薬治療と認知行動療法のそれぞれのメリットとデメリットのまとめである。



表2 ARMS への介入指針

- ・治療関係の成立と維持に焦点を当てる
- ・問題指向的アプローチを基本とする
- ・焦点となる問題に応じて、薬物療法、ケアマネジメント、認知行動療法的技法、支持的技法、家族介入を組み合わせる
- ・治療セッションには十分な時間をかける
- ・統合失調症への発展を前提とせず、回復に焦点を当てた治療を心がける

### 3. 東北大学 SAFE こころのリスク外来

PACE 同様の基準を用いた ARMS に対する早期介入サービスは、現在は欧米豪だけではなく、シンガポール、香港、韓国などのアジア諸国にも広がるなど世界規模で浸透しつつある。そこで、本邦においても、PACE 基準を用いた ARMS への早期介入サービスを実践する目的で、東北大学病院精神科内に、ARMS に対する早期介入を目的とした専門外来「SAFE こころのリスク外来」が2004年秋に開設された。サービスは、科内限定の試行的な段階から始まり、2005年春からは外部からの受け入れも開始した。スタッフは、精神科医3名と臨床心理士1名により構成されている。専門外来について関連機関に周知するためにパンフレットを作成し、送付したり、ホームページ (<http://safe-youthcentre.jp/>) を開設し、ARMS や精神病についての情報や専門外来の案内などを掲載している。

専門外来でのインテイク面接は、原則的に完全予約制としており、本人や家族からの直接の問い合わせの場合は、電話によるスクリーニングを実施している。対象年齢は14歳から35歳とし、抗精神病薬の服用歴の有無は問わない。診断基準はPACEの基準に準拠しており、アセスメントや診断のためにはPACEで開発されたARMSの包括的評価 (Comprehensive Assessment of ARMS; CAARMS)<sup>10)</sup> の日本語版を作成し使用している。インテイク時のアセスメントには、通常、60～90分の時間をかけた面接を1～2回実施している。ARMSに該当する場合には、「こころ

表3 ARMS への薬物療法の指針

- ・向精神薬の使用は必要最小限とする
- ・患者との台意を重視する
- ・前景に立つ症状に合わせて薬剤を選択する
  - 抑うつ、社会不安、強迫などに対してはSSRI
  - 不眠、内的不穏、焦燥などにはベンゾジアゼピン系
- ・抗精神病薬の使用は、原則的に下記に限定
  - 深刻な焦燥、自殺念慮、または興奮、暴力
  - 精神病症状に圧倒されている場合
  - 精神病症状が急速に進展する場合
- ・抗精神病薬を使用する場合は新規抗精神病薬を少量投与
- ・症状が安定している場合には、抗精神病薬の減量、中止を検討

のリスク状態」などという用語を用いて、治療が必要な状態であることや、治療を行わない場合のリスクなどについて、患者や家族にわかりやすい言葉で説明する。

治療介入については、海外の主要な介入サービスでの推奨やガイドライン<sup>5-7,12,13)</sup> を参考にした介入指針を作成し (表2, 3)、その上で個々の事例に合わせた個性性の高いアプローチを実施している<sup>9)</sup>。面接には十分な時間をかけるようにし、特に初期のセッションでは30～60分の時間をかけたセッションを必要に応じて毎週あるいは2週に1回実施する。問題指向的なアプローチを採用しており、患者にとって優先度の高い問題を検討し、その問題解決に共同で取り組む姿勢を重要視しており、対象者が継続的に治療を続けられるような関係づくりに配慮している。心理的治療<sup>11)</sup> は、EDIEで実施された認知療法<sup>6)</sup> に準拠したアプローチをとるようにしているが、主治医である精神科医が様々な役割を担うという本邦での現状に即し、認知療法の治療構造については、個々の症例に応じて柔軟に修正を加えるようにしている。ARMSでは、抑うつや不安など様々な精神症状が出現し、思春期・青年期特有の発達課題と関連した現実的な問題に悩みを抱えていることも多く、心理的治療の役割は大きいと考えられる。

向精神薬の使用は必要最小限とし、緊急性が乏しい場合には薬を使用しない観察期間をおいてか

表4 紹介元の内訳（人）

	全紹介者	ARMS 例
当院精神科	46	25
他の病院・診療所	24	17
大学等の相談室	7	5
臨床心理士	2	2
本人・家族	5	2
その他	1	0

ら必要性を判断するようにしている。実際、向精神薬を使わずにじっくり話しを聞く面接を数回行うことで、病状が比較的速やかに改善する例に遭遇することもしばしばである。向精神薬を用いる場合には、個々の症例ごとに標的とする症状を絞り込み、症状に応じてマイナー・トランキライザーやSSRI、新規抗精神病薬等を用いる。抗精神病薬の使用は、表3の原則に従うようにしている。

#### 4. インテイク時データと6ヶ月間での介入結果

サービス開始から2007年冬までに85名（男：女、34：51）のアセスメントを行い、51名（男：女、18：33）がARMSの基準を満たした。平均年齢は19.9±4.5歳で、高校生や大学生などの学生が35名を占めており、思春期から青年期にかけての若者が多く受診していることがわかる。男女比については、諸外国のデータでは、男女比はほぼ1：1か男性の割合が若干高くなることが多いが、われわれのサービスでは全受診者、ARMS例とも女性が多くなっている。紹介元は、表4の通りである。当院精神科内からの紹介が約半分を占めており、他施設からの紹介の割合はまだ不十分である。今後は精神医療関連施設、教育関連施設、一般の若者やその親などへ向けた啓発活動を強化していく必要がある。一方、精神科医からの紹介が多くを占めているせいもあり、アセスメントを行った者のARMSへの適合率は60%と比較的高い割合となっている。

ARMSの下位分類は表5の通りであり、多くは被害関係念慮や知覚異常などの微弱な陽性症状を呈して外来を受診していた。前医の診断が確認

表5 CAARMSによる診断の内訳（人）

ARMS 例	51
閾値下精神病群	41
素因・状態群	2
合併群：短期間欠性精神病/閾値下精神病	2
合併群：素因・状態/閾値下精神病	6
非ARMS 例	32
精神病（統合失調症など）	12
その他の精神障害（適応障害、不安障害など）	20

できた約2/3の症例では、統合失調症などの精神病性障害、ARMS、あるいはその疑いなどの診断がつけられていた。併存症状に基づいたDSM-IV診断では、海外での報告同様<sup>18)</sup>、大うつ病性障害、社会不安障害、強迫性障害などが多くを占めた。症例によっては、気分障害や不安障害を主診断と考え、精神病性の症状をそれに併存する症状として捉えることが適切かと思われる例も認められた。

これまでに33名の6ヶ月間の追跡調査を終了しており、このうち4名（12.1%）が精神病の基準を満たす状態に移行した。インテイク時に抗精神病薬服用歴のなかった20名では、3名（15.0%）が精神病に移行した。この移行率は、治療介入を行っている海外でのARMSの6ヶ月間での精神病移行率とほぼ同等の数値となっている。一方、6ヶ月を経過した後に精神病に移行する例も存在しており、この数値は介入後短期間での移行率として捉えるべきであり、介入をしなかった場合や、さらに長期間の介入を行った場合の精神病移行率はさらに高いと推定される。一方、精神病に移行しなかった症例の多くは、6ヶ月間で症状や機能が軽度～中等度改善していた。前医からの投薬が継続されていた症例を含む33名の6ヶ月間の薬物療法について調べたところ、新規抗精神病薬を2ヶ月以上投与されたのは13名で、SSRIは11名、睡眠薬を含むベンゾジアゼピン系薬物は22名であった。6ヶ月の間に精神病に移行した4名はすべて精神病移行前に抗精神病薬を2ヶ月以上投与されていた。

### おわりに

291名のARMSを追跡調査した北米の多施設による報告<sup>9)</sup>によれば、ARMSと診断される者のうち精神病に移行した者の割合は、6ヶ月で約13%、1年で約22%、2年半では約35%であった。この調査では、治療方法は標準化されておらず、それぞれの治療者が独自に治療を行っており、対象者の約35%に抗精神病薬が投与されていた。この報告にみられるように、ARMSが、精神病のハイリスク者を規定する概念として有効性をもつことは徐々に明らかになってきているが、治療方法については、どのような治療法が最善であるのかその結論は得られていない。治療的な介入を行った場合に、約65%は精神病に移行しないという逆の数値から考えた場合には、ARMSすべてに対して精神病の予防という観点だけから介入することには、矛盾が生じてくるかもしれない。したがって、ARMSへの早期介入を正当化するためには、患者が目下経験している症状や問題の解決に取り組むというもうひとつの目的にも十分に目を向けるべきであり、この目的の達成は結果的に精神病の予防に結びつくことになると考えられる。

このための介入戦略の選択肢のひとつとして抗精神病薬治療は、重要な役割を占めていることは確かである。しかし、副作用、服薬アドヒアランスの低さ、偽陽性例への投与などの問題を考慮した場合には、その使用方法については、今後、十分に検討を重ねていく必要があると思われる。われわれの経験からは、薬物療法の施行の有無にかかわらず、治療初期に特に重点的に取り組む心理的なアプローチは、きわめて重要であると考えられる。ただし、現在の本邦の標準的な精神医療の環境においては、われわれが行っているような時間をかけた診療は一般的には困難なことを考えると、海外のように臨床心理士などを育成し、臨床現場で実践的に活躍できるような環境を整備していく必要があると思われる。

ARMSと診断される若者の多くは、心理社会的な困難に直面して精神病性の症状を経験する。

この場合、ARMSで経験されるような精神病性の症状は、精神病へ移行するリスクを押し量る徴候のひとつでもあるが、周囲からの手助けを必要とする精神的な危機に瀕して発せられる危険信号としてとらえることもできよう。精神病へ発展する危険性を考慮しながらも、ARMSにおいては、精神病に移行せずに回復する例も多く存在するという事実を踏まえ、問題解決と回復に焦点を当てた治療アプローチが望ましいと考えられる。今後は、精神疾患への早期介入の重要性を踏まえた啓発活動や、治療が必要な対象者が適切な治療サービスを受けられるようにするためのシステム作り<sup>10)</sup>が必要であると考えられる。

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