THE EUROPEAN SOCIETY OF MEDICINE
Medical Research Archives, Volume 14 Issue 5

RESEARCH ARTICLE

Diagnostic Accuracy of the Japanese Version of the GAD-2 for Screening Generalized Anxiety Disorder in Primary Care

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OPEN ACCESS

PUBLISHED
31 May 2026

CITATION
Muramatsu, K., Miyaoka, H., et al., 2026. Diagnostic Accuracy of the Japanese Version of the GAD-2 for Screening Generalized Anxiety Disorder in Primary Care. Medical Research Archives, [online] 14(5).

ISSN
2375-1924

ABSTRACT

Objective: To evaluate the diagnostic performance of the Japanese version of the Generalized Anxiety Disorder 2-item scale as an ultra-brief screening instrument for detecting generalized anxiety disorder in primary care settings.

Methods: This study is a secondary analysis of data from a previously conducted validation study of the Japanese version of the Generalized Anxiety Disorder 7-item scale. In the original study, participants completed the 7-item questionnaire and subsequently underwent a structured diagnostic interview using the Mini-International Neuropsychiatric Interview-Plus (MINI-Plus). The first two items of the 7-item scale were used to derive the Japanese version of the Generalized Anxiety Disorder 2-item scale. Diagnostic accuracy was evaluated using receiver operating characteristic analysis, sensitivity, specificity, positive likelihood ratios, and stratum-specific likelihood ratios. Construct validity was examined using the Mental Component Summary score of the Short Form-8 Health Survey.

Results: Receiver operating characteristic analysis demonstrated excellent discrimination ability of the Japanese version of the Generalized Anxiety Disorder 2-item scale (area under the curve = 0.902). The optimal cut-off value was ≥3, yielding sensitivity of 82.3%, specificity of 81.2%, and a positive likelihood ratio of 4.6 (95% CI, 3.0–7.1). The stratum-specific likelihood ratios for scores of 0–2, 3–4, and 5–6 were 0.23 (95% CI, 0.14–0.37), 2.48 (95% CI, 1.41–4.38), and 14.38 (95% CI, 4.9–41.51), respectively. Higher generalized anxiety disorder severity was significantly associated with lower Short Form-8 Mental Component Summary scores ($U = 882.5$, $Z = -7.234$, $P < .001$).

Conclusions: The Japanese version of the Generalized Anxiety Disorder 2-item scale is a brief and clinically useful screening instrument for detecting generalized anxiety disorder in primary care settings. In addition to screening utility, its score ranges provide clinically meaningful information for risk stratification and may support stepwise screening approaches in busy clinical settings.

Keywords: generalized anxiety disorder, diagnostic accuracy, anxiety screening, ROC curve, primary care, Japan

Introduction

Anxiety disorders are among the most common mental health conditions worldwide and represent a major public health concern. In primary care settings, patients with anxiety disorders frequently present with somatic complaints rather than explicitly reporting psychological distress, which may lead to underrecognition of these conditions. Consequently, efficient screening strategies for identifying generalized anxiety disorder (GAD) in primary care populations are of considerable clinical importance. Brief screening instruments that can be easily incorporated into routine consultations are essential for improving the detection of anxiety disorders in primary care.

Epidemiological research indicates that anxiety disorders are highly prevalent worldwide. In the United States, large-scale population surveys have estimated that more than one-quarter of adults experience an anxiety disorder during their lifetime.[1] Among the various anxiety disorders, GAD is one of the most frequently encountered conditions. In primary care populations, the prevalence of GAD has been reported to be relatively high.[2] Previous studies in Japan suggest that anxiety disorders occur at comparable rates. [3]

Recognizing the clinical importance of anxiety disorders, the US Preventive Services Task Force (USPSTF) evaluated the evidence regarding routine screening for anxiety disorders in adults. The USPSTF concluded that screening for anxiety disorders in adults younger than 65 years provides a moderate net benefit and therefore recommended routine screening in primary care settings.[4,5] Efficient screening instruments that can be easily implemented during routine consultations are of considerable value. Brief questionnaires may facilitate the identification of anxiety disorders in primary care settings.

Among these instruments, the Generalized Anxiety Disorder-7 (GAD-7) scale, developed by Spitzer, Kroenke, and colleagues, is one of the most widely used self-report measures for screening GAD.[6] The GAD-7 has demonstrated strong diagnostic performance and has been validated in a variety of languages and clinical populations .[7,8]

The Japanese version of the GAD-7 (J-GAD-7) was translated, and its accuracy was confirmed through a back-translation process verified by Kroenke and Spitzer .[9] The J-GAD-7 has been used in clinical and research settings in Japan to assess anxiety symptoms in primary care patients.

The Generalized Anxiety Disorder 2-item (GAD-2) scale was developed as an ultra-brief screening instrument derived from the first two core items of the GAD-7.[6] Because it consists of only two questions, the GAD-2 can be administered rapidly and may be particularly suitable for routine screening in busy clinical environments. Previous international validation studies suggest that the GAD-2 demonstrates acceptable sensitivity and specificity for detecting GAD across diverse populations .[7,8] Recent meta-analytic evidence has also indicated that the GAD-2 retains good overall diagnostic accuracy despite its brevity .[10]

Although the GAD-2 has been widely used and studied internationally, evidence regarding the diagnostic performance of the Japanese version of the GAD-2 (J-GAD-2) remains limited. Because the J-GAD-2 is directly derived from the validated J-GAD-7, evaluating its diagnostic performance in Japanese primary care populations is an important step toward efficient screening strategies for anxiety disorders in routine clinical practice.

Therefore, the present study examines the diagnostic accuracy of the J-GAD-2 for detecting GAD in primary care settings in Japan, using the Mini-International Neuropsychiatric Interview-Plus (MINI-Plus) as the reference standard.

Methods

STUDY DESIGN

This diagnostic accuracy study represents a secondary analysis of data from a previously conducted validation study of J-GAD-7, and was reported in accordance with the Standards for Reporting Diagnostic Accuracy Studies (STARD) 2015 guidelines. In the original validation study, participants first completed the J-GAD-7 questionnaire and subsequently underwent a structured psychiatric diagnostic interview using the Mini-International Neuropsychiatric Interview (MINI-Plus). The MINI-Plus diagnosis of GAD served as the reference standard.

For the present analysis, the two core items corresponding to the GAD-2 were extracted from the responses to the J-GAD-7 questionnaire to derive the J-GAD-2. The diagnostic accuracy of the J-GAD-2 for detecting GAD was then evaluated.

PARTICIPANTS

Subjects were recruited between April and July 2010 in four primary care clinics, two general hospitals, and one psychiatric hospital. Recruitment and assessment were conducted by a team consisting of eight physicians, one psychiatrist, three clinical psychologists, and one mental health social worker.

A total of 176 adult patients attending routine clinical visits were approached for participation. Of these, 161 individuals (91.5%) completed the J-GAD-7 questionnaire and were included in the analysis. The mean age of participants was 41.34 years (SD = 14.38). The sample consisted of 55 men and 106 women. Most participants (n = 151) also completed the Short Form-8 Health Survey (SF-8) to assess health-related quality of life. Missing data for the SF-8 were negligible.

After completing the questionnaire, participants underwent a structured diagnostic interview using the Japanese version of the MINI-Plus. Interviewers conducting the diagnostic assessment were blinded to the results of the screening questionnaire to reduce diagnostic expectation bias.

JAPANESE VERSION OF THE GENERALIZED ANXIETY DISORDER 2-ITEM SCALE

The Japanese version of the Generalized Anxiety Disorder 2-item scale was derived directly from the

Japanese version of the Generalized Anxiety Disorder-7 (J-GAD-7). Specifically, it consists of the first two items of the J-GAD-7, which correspond to the core symptoms of generalized anxiety disorder. The J-GAD-7 used in the original study was translated from the original English version by Muramatsu K and verified through a back-translation procedure conducted by Kroenke and Spitzer. Each item is scored from 0 ("not at all") to 3 ("nearly every day"), yielding a total score ranging from 0 to 6, with higher scores indicating greater severity of anxiety symptoms.

PSYCHIATRIC INTERVIEWS

The Mini-International Neuropsychiatric Interview (MINI)-Plus was used as the reference standard for diagnosing GAD. The MINI was originally developed as a brief structured diagnostic interview compatible with DSM-IV-TR and ICD-10 criteria[10].

The Japanese version of the MINI has demonstrated good reliability and validity in previous studies [11]. To diagnose GAD and rule out confounding disorders, we used the MINI-Plus.

ADDITIONAL MEASURE

Health-related quality of life was assessed using the Japanese version of the Short Form-8 Health Survey (SF-8). The SF-8 is a shortened form of the SF-36 Health Survey Scale that yields comparable eight-dimension health profiles and summary scores for the physical and mental components of health.

Using the standardized Japanese version of the SF-8, we calculated two summary scores, physical component summary (PCS) and mental component summary (MCS), in accordance with the established scoring rules of the SF-8 Japanese version .[12] The Mental Component Summary (MCS) score was used to examine the construct validity of the J-GAD-2.

STATISTICAL ANALYSIS

Diagnostic accuracy of the J-GAD-2 for detecting GAD was evaluated by sensitivity, specificity, positive likelihood ratios, and receiver operating characteristic (ROC) curves with corresponding areas under the curve (AUCs) and 95% confidence intervals. Stratum-specific likelihood ratios (SSLRs) were calculated for predefined score ranges of the J-GAD-2 (0–2, 3–4, and 5–6) to estimate the change in probability of GAD across score strata[13]. The optimal cut-off score was determined based on the balance between sensitivity and specificity. We assessed construct validity by comparing SF-8 Mental Component Summary (MCS) scores between J-GAD-2 severity groups (0–2 vs 3–6) using the Mann–Whitney U test. A cut-off score of ≥3 was considered a positive screening result, and scores ≤2 were considered negative.

Results

DIAGNOSTIC ACCURACY

Receiver operating characteristic (ROC) analysis demonstrated excellent discrimination of the J-GAD-2 for detecting generalized anxiety disorder, with an area under the curve (AUC) of 0.902.

Figure 1. Participant flow diagram according to the Standards for Reporting of Diagnostic Accuracy statement.

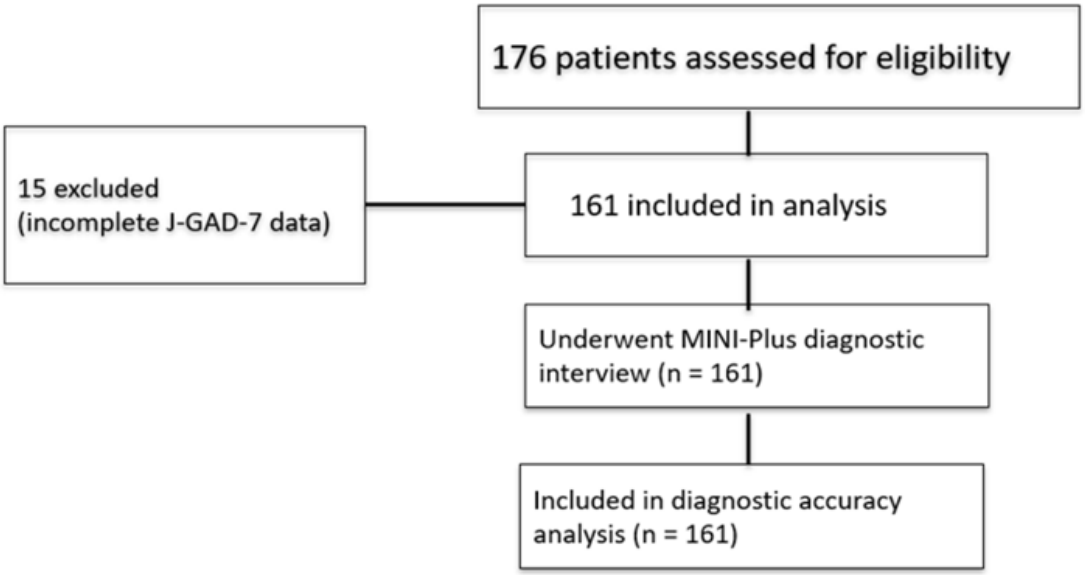
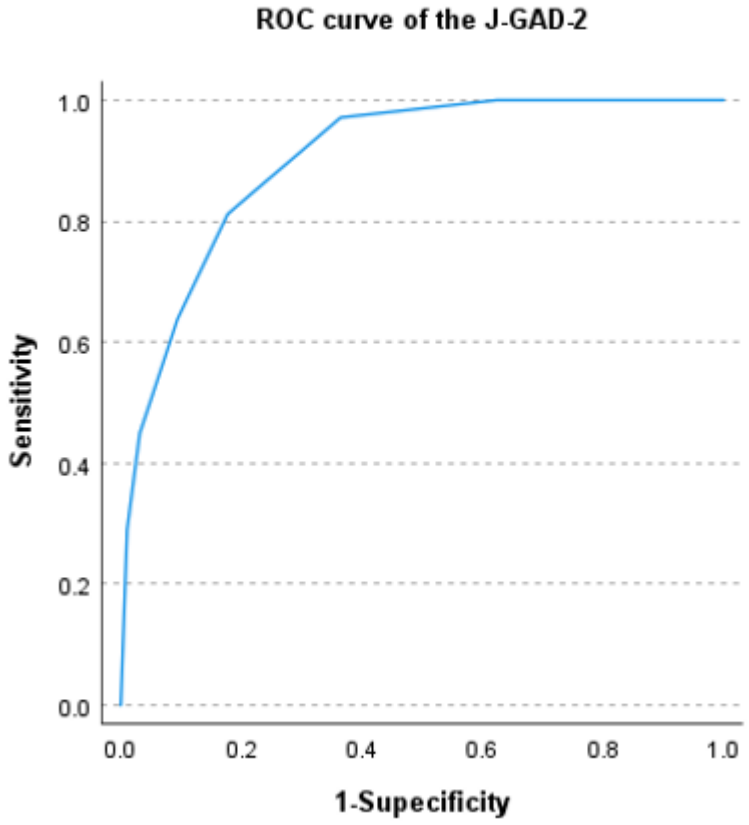


Figure 2. Receiver operating characteristic curve of the Japanese version of the Generalized Anxiety Disorder 2-item scale



Among the evaluated thresholds, a cut-off score of ≥3 provided the best balance between sensitivity and specificity, yielding a sensitivity of 82.3% and a specificity of 81.2%. The corresponding positive likelihood ratio was 4.6 (95% CI: 3.0–7.1). Increasing the cut-off score improved specificity but reduced sensitivity. When the threshold was raised to ≥4, specificity increased to 90.6%, whereas sensitivity decreased to 63.8%, yielding a likelihood ratio of 6.8 (95% CI: 3.6–12.8). A higher cut-off score of ≥5 produced very high specificity (96.9%) but substantially reduced sensitivity (44.9%), with a likelihood ratio of 14.4 (95% CI: 5.0–41.5).

Table 1. Operating Characteristics of Various Cut-off scores of the Japanese version of the Generalized Anxiety Disorder 2-item Scale for Detecting Generalized Anxiety Disorder

J-GAD-2 Cut-off	Sensitivity (%)	Specificity (%)	Positive Likelihood Ratio	95% CI
≥2	97.1	63.5	2.7	2.0–3.5
≥3	82.3	81.2	4.6	3.0–7.1
≥4	63.8	90.6	6.8	3.6–12.8
≥5	44.9	96.9	14.4	5.0–41.5

GAD, generalized anxiety disorder; CI, confidence interval.

Scores of 0–2 were associated with an SSLR of 0.23 (95% CI: 0.14–0.37), indicating a low probability of GAD. Scores of 3–4 corresponded to an SSLR of 2.48 (95% CI: 1.41–4.38), suggesting a moderate increase in the likelihood of GAD. Scores of 5–6 yielded an SSLR of 14.38 (95% CI: 4.9–41.51), indicating a markedly increased probability of GAD.

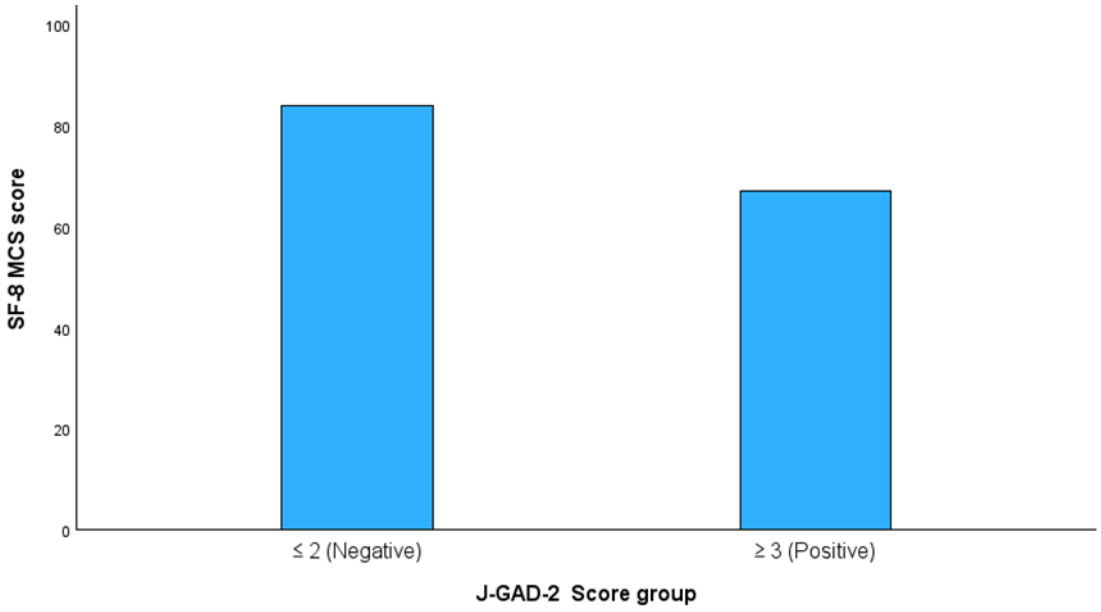
Table 2. Stratum-Specific Likelihood Ratios for the Japanese version of the Generalized Anxiety Disorder 2-item Scale Severity Scores

J-GAD-2 Score	GAD Positive by MINI-Plus	GAD Negative by MINI-Plus	SSLR (95% CI)
0–2	13	79	0.23 (0.14–0.37)
3–4	25	31	2.48 (1.41–4.38)
5–6	14	3	14.38 (4.9–41.51)

SSLR: stratum-specific likelihood ratio; MINI-Plus: Mini International Neuropsychiatric Interview-Plus.

Participants were categorized into two groups according to J-GAD-2 scores (0–2 vs 3–6). The Mann–Whitney U test demonstrated a significant difference in SF-8 MCS scores between the groups ($U = 882.5$, $Z = -7.234$, $p < .001$). Participants with higher J-GAD-2 scores showed significantly lower SF-8 MCS scores, indicating poorer mental health-related quality of life.

Figure 3. SF-8 Mental Component Summary (MCS) scores according to J-GAD-2 score groups.



Discussion

The present study demonstrated that the J-GAD-2 has excellent diagnostic accuracy for detecting generalized anxiety disorder in Japanese primary care settings, with an AUC of 0.902 and an optimal cut-off score of ≥3. This cut-off provided a balanced sensitivity and specificity and is consistent with the threshold recommended in the original GAD-2 validation study and supported by recent meta-analytic evidence.[7,8]

The present findings are also consistent with previous international validation studies of the GAD-2, including those conducted in Chinese populations, which have similarly reported good diagnostic performance and supported a cut-off score of 3 for identifying probable generalized anxiety disorder.[14] These findings suggest that the diagnostic properties of the GAD-2 are broadly stable across linguistic and cultural contexts. In addition to demonstrating screening utility, the stratum-specific likelihood ratio analysis indicated that increasing J-GAD-2 score ranges were associated with progressively higher probabilities of generalized anxiety disorder. This finding suggests that the J-GAD-2 may provide clinically meaningful risk stratification beyond simple dichotomous screening.[13]

From a clinical perspective, the brevity of the J-GAD-2 makes it particularly suitable for routine use in busy primary care settings. Patients with positive screening results may subsequently undergo more detailed assessment using the full J-GAD-7 or a structured diagnostic interview. This stepwise screening approach is consistent with international clinical guidance, including NICE guidance on anxiety screening in perinatal mental health settings, which suggest further assessment with the GAD-7 when the GAD-2 score is 3 or higher.[15] Such an approach may improve the efficiency of anxiety disorder detection while reducing respondent burden in routine clinical practice.

Several limitations should be noted. First, this study was a secondary analysis of data originally collected for validation of the J-GAD-7, and the J-GAD-2 scores were derived from the first two items of the J-GAD-7 rather than administered independently. However, this approach is consistent with the original development methodology of the GAD-2.[7] Second, the study sample was drawn from Japanese primary care settings and may not fully represent other clinical or community populations. Future studies should examine the performance of the J-GAD-2 in broader populations and clinical settings.

Conclusion

The Japanese version of the Generalized Anxiety Disorder 2-item scale is a brief and clinically useful screening instrument for detecting generalized anxiety disorder in Japanese primary care settings. In addition to its role as an initial screening tool, the J-GAD-2 score ranges provide clinically meaningful information for risk stratification. The J-GAD-2 may therefore be particularly useful as the first step in a stepwise screening strategy for anxiety assessment in busy clinical environments.

Conflict of interest

No competing interests are declared by authors.

Role of funding source

This research was supported by AMED under Grant Number JP23rea522113h.

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