

Global Assessment of Medication Adherence: Correlational Analyses of a Brief Tool for Evaluating Medication Adherence in Patients with Severe Mental Disorders

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ABSTRACT

Background: Assessment of medication adherence of patients with severe mental disorders is an important aspect of long-term treatment. There is a need for a brief and practical tool to assess medication adherence. This study investigates the clinical, functional, and validation correlations of a short and easy-to-use tool.

Methods: Global Assessment of Medication Adherence (GAMA) was prepared as a single item with 5 severity degrees, from complete adherence (1 point) to complete nonadherence (5 points). The scale was applied to patients with severe mental illnesses receiving outpatient and inpatient treatment. The GAMA scores were compared with psychopathology, clinical severity, insight, and functionality scale scores. While the validity analyses were tested with face, convergent, and criterion validity, interrater reliability was used for the reliability analysis.

Results: Data from 70 outpatients and 14 inpatients were examined. In the analyses performed for convergent validity, a positive correlation was found between GAMA scores and psychopathology ($r = 0.646$, $P < .001$), and clinical severity ($r = 0.692$, $P < .001$), and a significant negative correlation was found between GAMA scores and insight ($r = -0.793$, $P < .001$), and functionality ($r = -0.740$, $P < .001$). There was a significant difference in the GAMA scores of 14 patients assessed during hospitalization and discharge. A high positive correlation was found between the GAMA measurements of the psychiatrist and the nurse at admission and discharge.

Conclusion: This study shows that the GAMA has sufficient psychometric properties for assessing medication adherence. Due to its brevity, simplicity, and validity, the scale is appropriate for use in routine clinical practice and research.

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INTRODUCTION

Medication adherence is defined as the ability of patients to start using medications as prescribed, continue using them with proper dosing, and discontinue them when the time comes as recommended.¹ The term compliance is also used interchangeably in research and clinical practice to convey a similar meaning to adherence.^{1,2} Accurately assessing patients' adherence to treatment will lead to a more accurate determination of the dose-response relationship and treatment effectiveness. For this reason, it is emphasized that treatment adherence should be evaluated regularly in clinical settings.³

Serious problems may be experienced in medication adherence, especially in chronic mental illnesses with

impaired insight (schizophrenia, schizoaffective disorder, bipolar affective disorder, and delusional disorder).⁴ It has been reported that adherence to antipsychotic treatment is often poor; between 40% and 60% of patients do not take medication as prescribed.⁴⁻⁸ The degree of nonadherence in the same individual may also change over time. Complete adherence, partial adherence, or complete nonadherence may vary depending on individual and environmental factors.⁹ Studies conducted on drug records (pill counts) have shown that less than 80% adherence with the recommended treatment leads to exacerbations and rehospitalizations.^{7,10} Low adherence rates can lead to severe consequences such as relapse of the illness, rehospitalization, poor

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functioning, increased disability, violence, risk of suicide, and wastage of healthcare resources.¹⁰⁻¹⁴ It is reported that nonadherence to medication treatment is related to some factors such as poor insight, delusional symptoms and suspiciousness, cognitive impairments, substance abuse, poor therapeutic alliance, problems accessing treatment, medication side effects, low level of education, low socioeconomic status, perceived stigma, and young age.^{4,15-17} In nonadherence to treatment, especially lack of insight, hostility, and substance abuse are mostly emphasized.¹⁷ In the CATIE study, lack of insight was found to be the main reason for nonadherence to medication treatment.¹⁴ In this study, the criterion for nonadherence was taken as taking less than 80% of the prescribed drug dose in a month, as in previous studies.^{7,10}

Evaluation of treatment adherence in clinical practice should be considered important in preventing nonadherence and possible negative consequences. However, the lack of enough time for the clinicians often causes this practice to be ignored. Following a good treatment collaboration with patients, the appropriate treatment approach would be to inquire about adherence to medication treatment at each meeting, discuss experiences with medication(s), and identify situations or attitudes that may lead to nonadherence and seek solutions. It is expected that the use of a short measurement tool designed to be suitable for clinical study will have a direct impact on treatment results, especially in the follow-up of individuals with severe mental illnesses.^{3,5}

Although patients' attitudes and behaviors toward medication or treatment are important in assessing adherence, it is known that the actual behavior is given more importance by clinicians.³ Considering a significant proportion of patients who are completely or partially nonadherent, the importance of the information received from caregivers or family members becomes evident. Patients may not take their medications on some days or may take inadequate doses. To prevent this situation from being overlooked, it is recommended that medication adherence be assessed monthly, and even more frequently if symptoms increase.³

Tools that evaluate medication adherence are roughly divided into two categories: subjective and objective. Subjective tools consider patients' self-reports, reports of

caregivers or family members, and clinician evaluations. Objective tools evaluate direct oral control, pill counting, electronic monitoring, or biochemical measurements (body fluids such as blood and urine).^{2,18} Many tools and methods have been developed for evaluating adherence to medication in psychiatric practice.² Cost-effectiveness, time usage, and practicality gain importance in evaluation. Although objective (direct) evaluation is more reliable,^{2,19} subjective (indirect) evaluation made by the patient or clinician is cost-effective and easy to apply, leading to more frequent usage.¹⁸

The Medication Adherence Rating Scale (MARS) is commonly used in psychiatric practice.²⁰ This scale, which combines the Drug Attitude Inventory²¹ and the 4-item Morisky Medication Compliance Scale (4-item),²² consists of 10 items and 3 subscales (medication adherence behavior, attitude to taking medication, and negative side effects, and attitudes to psychotropic medication). This assessment tool is one that the patient fills out themselves. Although this method is easy to apply, its reliability is questionable. Another scale is the Brief Adherence Rating Scale.²³ In this scale, the first 3 items include information from patients such as "how many days in the last month no medication was taken, how many days less than half of the recommended dose was taken," and what percentage of the recommended dose has been received (e.g., 70%) by the patient is determined by the clinician's judgment.

Another short and practical assessment tool for medication adherence was used by Kemp et al.²⁴ in a study conducted in 1998. The Compliance Assessment has a score ranging from 1 to 7 (a higher score indicates higher compliance) and was applied by nurses working in the clinic. A change in patients treated for more than 18 months was observed in this assessment. However, the relationship between this assessment and the other scales has not been evaluated. When considering the 2 scales frequently used to evaluate psychopathology and functionality in clinical practice (Clinical General Impression and Global Assessment of Functioning), it could be argued that it is possible to easily evaluate treatment compliance without causing a waste of time.²⁵⁻²⁷ A similar rating of compliance used in the study by Kemp et al could be an approach that can be used in follow-up studies. In some studies conducted in Turkey, adherence to medication treatment was evaluated similarly with a 5-point rating.²⁸⁻³⁰

In this study, we aimed to develop a rating tool for medication adherence that can be easily and quickly applied in clinical practice, give reliable results, and be easily used by healthcare professionals in the field. With this assessment tool, the compliance of patients with psychotic symptoms, especially with antipsychotic drug treatment, will be quickly evaluated, and the necessary treatment arrangements can be made promptly to prevent the negative consequences that may arise from nonadherence.

MAIN POINTS

- Medication adherence is a significant problem, especially for patients with severe mental disorders.
- Adherence to medication is related to insight and psychopathology.
- The GAMA score is highly correlated with insight, psychopathology, and functioning.
- The GAMA scores of the inpatients are significantly different between admission and discharge.
- The GAMA is a valid and reliable tool for assessing medication adherence.

MATERIAL AND METHODS

Development of the Tool

Global Assessment of Medication Adherence (GAMA) was prepared as a single-item tool by a specialist group that has worked in the field of severe mental illnesses for many years. Clinical observations and literature knowledge were considered when creating the options in the scale. One of the two extreme dimensions of adherence to medication treatment was determined as the patient using the medicine regularly, spontaneously, without support from others, and the other one was never accepting the treatment and not using the medicine. These 2 extreme situations and the attitudes in between were defined in terms of their degree of severity. Complete adherence received 1 point, and complete nonadherence received 5 points. Evaluation degrees were made as follows:

1. *Completely adherent*: Takes medications regularly on his/her own. The patient uses medications as prescribed without needing any reminders or support. They can take measures to remind medication times or use reminders for medication use. Missing a few doses a month due to forgetfulness is not considered a problem.
2. *Mildly nonadherent*: Takes regularly with the help of others. The patient has no objection to the use of medication. However, it may need to be supported during usage. This might be due to inadequate insight, ongoing symptoms, poor cognitive abilities, or medication side effects. If the patient is not supported, there is a possibility that he/she will not receive adequate doses of their medications sometimes.
3. *Moderately nonadherent*: Takes irregularly or needs persuasion. The patient may object to taking medication. If medication use is left to them, they may use medications irregularly. If family members or caregivers monitor their medications use, some persuasion may be required to get them to take medications. Patients at this stage can easily discontinue drug treatment if left unsupervised.
4. *Severely nonadherent*: More persuasion is required, or intramuscular administration needs to be done. More persuasion is required compared to the previous stage; the patient is more questioning about drug use. They may insist on not taking oral medications. They may prefer to take his/her medications only from someone they trust. If they are not taking oral medication, treatment continues with intramuscular (IM) administration. Patients who receive mandatory IM drug treatment are evaluated in this group. Patients who continue their treatment with IM voluntarily are not considered in this group.
5. *Completely nonadherent*: Never accepts treatment, does not take medication. The patient does not

accept medication use in any way despite all kinds of persuasion efforts.

The explanations for grading from complete adherence to complete nonadherence were determined in accordance with the clinical experience of the specialists and the extent of suitability for daily practice. With this tool, the patient's adherence to medication treatment is evaluated through interviews, observations, and information obtained from the patient and their relatives.

Participants

The study was carried out with patients who were treated in the clinics of Kocaeli University School of Medicine, Department of Psychiatry, and who had accepted to participate in the study, during the period from March 2021 to March 2022. Criteria for inclusion in the study were determined as having a serious mental illness (schizophrenia, schizoaffective disorder, bipolar affective disorder, delusional disorder according to DSM-5),³¹ being at least a primary school graduate, being over 18 years of age, and giving consent to participate in the study. Ethical permission was obtained from Kocaeli University Non-invasive Clinical Research Ethics Committee (KÜ GOKAEK 2018/275). Participants were informed about the purpose and method of the study and their signed consent was obtained.

Measures

Positive and Negative Syndrome Scale (PANSS): It is a semi-structured interview scale with 30 items (7 are positive, 7 are negative, and 16 are general psychopathology symptoms) and a 7-point severity rating.³² The Turkish reliability and validity study of the scale was conducted.³³

Schedule for Assessing the Three Components of Insight (SAI): The scale consists of three components (compliance with treatment, awareness of having a mental illness, and the ability to relabel unusual mental events as pathological). A high score on the scale indicates a high level of insight.³⁴ Turkish validity and reliability study was done.³⁵

Clinical Global Impression-Severity (CGI-S): The scale includes grading from 1 to 7 (1 normal, not ill, 7 among the most severely ill) according to the severity of the illness.³⁶

General Assessment of Functioning (GAF): The psychosocial functionality of the patient is graded by giving points between 0 and 100, with a high score indicating high functionality.³⁷

Procedure

Among the patients participating in the study, 70 patients who were followed up at the outpatient clinic were administered PANSS, CGI-S, GAF, SAI, and GAMA by the researcher MBG (a psychiatrist). The PANSS, CGI-S, GAF, SAI, and GAMA (both at admission and at discharge) were

administered to the 14 patients monitored in the ward by the researcher SD (a psychiatrist), and at the same time, GAMA was administered by the researcher SY (a clinical nurse).

Statistical Analysis

The data of the study were analyzed using SPSS version 22.0 (IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.). The Kolmogorov-Smirnov test was used to assess the normality distribution of the variables. Descriptive statistics were expressed as mean \pm standard deviation for the normally distributed variables. Categorical variables were reported as n (%). When evaluating the data, the independent sample *t*-test was used to compare the means of measurable data of 2 independent groups. The one-way ANOVA *t*-test was used to compare the means of measurable data of more than 2 independent groups. While face, convergent, and criterion validity analyses were applied for validity, the inter-rater correlation was used for reliability analysis. The Pearson correlation coefficient was used to assess relationships between the demographic and clinical characteristics and other scale scores and the GAMA scores. The Mann-Whitney *U*-test was used to compare the means of GAMA scores applied at the patients' admission and discharge from the ward. The Spearman correlation coefficient was used to assess relationships between the GAMA scores of the Psychiatrist and the Nurse. The statistical significance level was accepted as $P < 0.05$.

RESULTS

In the study, data from 14 inpatients and 70 outpatients were examined. The demographic and clinical characteristics of the patients are shown in Table 1.

Validity

It was evaluated with face, convergent, and criterion validity.

Face Validity

The developed assessment tool has been used in patient monitoring at Kocaeli University, Department of Psychiatry, for a long time. In the evaluations made by the psychiatrists and the researchers who made up the research team, it was concluded that the item explanations of the assessment tool used were clear and understandable. This assessment tool has been used in clinical studies and has been observed to have a significant relationship with important clinical findings.²⁸⁻³⁰

Convergent Validity

The relationship between the score of the developed assessment tool and the scale scores that may be clinically relevant is shown in Table 2. It was found that there

Table 1. Demographic and Clinical Characteristics of the Patients (n=84)

Age (mean \pm SD)	33.22 \pm 10.26
Education (mean \pm SD)	11.61 \pm 2.94
Gender, male (n, %)	57 (67.9)
Marital status, single (n, %)	65 (77.4)
Diagnosis	
Schizophrenia (n, %)	62 (73.80)
Schizoaffective disorder (n, %)	15 (17.85)
Bipolar disorder (n, %)	3 (3.57)
Delusional disorder (n, %)	4 (4.76)
Age of illness onset (mean \pm SD)	23.55 \pm 8.00
Duration of illness (mean \pm SD)	9.75 \pm 7.33
Number of hospitalization (mean \pm SD)	2.39 \pm 1.97
Comorbidity	
None (n, %)	73 (86.9)
Major depressive disorder (n, %)	3 (3.6)
Obsessive compulsive disorder (n, %)	6 (7.1)
Other (n, %)	2 (2.4)

SD, standard deviation.

was a highly significant negative relationship between GAMA scores and SAI ($r = -0.793$, $P < .01$) and GAF ($r = -0.740$, $P < .01$) scores. In addition, a positive, moderately significant relationship was detected between the GAMA scores and CGI-S scores ($r = 0.692$, $P < .01$), PANNS positive symptoms subscale scores ($r = 0.626$, $P < .01$), negative symptoms subscale scores ($r = 0.331$, $P < .01$), general psychopathology subscale scores ($r = 0.636$, $P < .01$), and PANSS total score ($r = 0.646$, $P < .01$).

Criterion Validity

The results regarding the criterion validity of the assessment tool are shown in Table 3. During the study period, GAMA was applied to the patients treated in the inpatient ward

Table 2. Correlation Between GAMA Scores and Other Scale Scores (n=84)

	Mean \pm SD	Range	<i>r</i>	<i>P</i>
SAI	7.35 \pm 4.47	0-14	-0.793	<.001
PANSS positive	22.16 \pm 7.51	10-47	0.626	<.001
PANSS negative	22.17 \pm 5.44	12-36	0.331	.002
PANSS general psychopathology	44.76 \pm 10.30	20-72	0.636	<.001
PANSS total	89.10 \pm 20.22	46-140	0.646	<.001
Clinical global impression-severity	4.23 \pm 1.39	2-7	0.692	<.001
Global assessment of functioning	51.90 \pm 11.43	25-70	-0.740	<.001
Global assessment of medication adherence	2.34 \pm 0.97	1-5	-	

PANSS, Positive and Negative Syndrome Scale; *r*, Pearson coefficient; SAI, Schedule for Assessing the Three Components of

(schizophrenia=8, schizoaffective disorder=3, bipolar affective disorder=1, delusional disorder=2) at admission and discharge. Scores at admission and discharge were compared. Two assessments were performed on a total of 14 patients (mean age=34.5 ± 14.07; 57% women, 21.4% married, mean years of education=11 ± 3.08; mean illness duration=7.21 ± 5.35 years). It was determined that there was a significant difference between measurements ($P=.002$).

Reliability

The reliability of the assessment tool was assessed by the inter-rater correlation coefficient. The evaluation tool was filled out by both the psychiatrist and the psychiatric clinical nurse at the admission and discharge of 14 patients hospitalized in the inpatient ward during the study period. A highly significant positive relationship was detected between the scores assessed by the researchers at both admission and discharge ($P < .001$ and $P=.008$, respectively) (Table 4).

Association with Sociodemographic and Clinical Characteristics

The relationship between GAMA score and sociodemographic and clinical characteristics is shown in Table 5. There was a significant relationship between the score of the assessment tool and the age of illness onset ($r = 0.236$, $P=.031$). No significant difference was found according to gender, age, marital status, years of education, illness duration, number of hospitalizations, and comorbid mental illness variables.

DISCUSSION

Even though various assessment tools measure medication adherence, clinicians require a tool that can make effective measurements in a short time.³ Our study arose from the need to evaluate patients' adherence to recommended drug treatment in a short time and almost accurately in their routine clinical evaluations. It was determined that the scale provides adequacy in face, convergent (Table 2), and criterion validities (Table 3). The consistency of the assessment of the patients by the 2 different professionals during both admission and discharge also shows that the scale is reliable (Table 4).

The GAMA, which was developed with a 5-severity degree in a single item, is rated by a healthcare professional

Table 3. The GAMA Scores' Change in Hospitalized and Discharged Patients (n=14)

	Admission	Discharge	P
GAMA-psychiatrist (mean ± SD)	3.42 ± 1.39	2.07 ± 1.14	.002
GAMA-nurse (mean ± SD)	3.14 ± 1.46	1.78 ± 0.97	.002

SS, standard deviation.

Table 4. The GAMA Scores' Correlation Between the Psychiatrist and Nurse (n=14)

		GAMA-Nurse	
		Admission	Discharge
GAMA-Psychiatrist	r_s	0.902	0.677
	P	<.001	.008

r_s , Spearman correlation coefficient.

who has knowledge of the patient's medication use. Although the clinician-rated scale includes subjectivity, it provides an evaluation decision made as a result of clinical monitoring along with information obtained from the patient himself and his relatives. This ensures that the scale is as informative as possible. It also has a mediating role in establishing an alliance between the patient and the therapist.

The fact that medication adherence showed a high positive correlation with psychopathology and a negative correlation with insight demonstrated that GAMA is a valid measurement tool. The relationship between insight and treatment adherence was evaluated in both the CATIE (with the insight scale) and the EUFEST study (with the insight item of PANSS). In the CATIE study, improvement in insight was associated with increased compliance with treatment, and in the EUFEST study, impaired insight was associated with noncompliance with medication.^{17,38} Additionally, in a multicenter study examining insight and compliance with medication treatment in patients with schizophrenia and bipolar disorder, a strong relationship was found between insight and medication compliance.³⁹ From this point, compliance with medication treatment could be considered an indicator of insight.

The scale showed a strong relationship between an improvement in psychopathology and increased

Table 5. Relationship of the GAMA Scores with Demographic and Clinical Characteristics (n=84)

Demographic and Clinical Characteristics	GAMA Scores	Statistics
Gender ¹ /male	2.24 ± 0.87	$P=.175$
Age ²	2.34 ± 0.97	$r=0.091$ $P=.412$
Education ²	2.34 ± 0.97	$r=-0.130$ $P=.239$
Marital status ³ /single	2.30 ± 0.93	$P=.228$
Age of illness onset ²	2.34 ± 0.97	$r=0.236$ $P=.031$
Duration of illness ²	2.34 ± 0.97	$r=-0.107$ $P=.331$
Number of hospitalization ²	2.34 ± 0.97	$r=0.010$ $P=.928$
Comorbidity ¹ /none	2.26 ± 0.92	$P=.096$

¹Independent sample *t*-test.

²Pearson correlation coefficient.

³One-way ANOVA test.

functionality in 14 patients based on inpatient treatment. When evaluated together with the high correlation in the data of all patients, it can be said that the scale is valid. At the same time, the high consistency of interrater scoring both at admission and discharge showed that it is reliable.

Scale items were used with the same degree of severity, but categorically, in some studies conducted in Turkey. In all 3 studies, a significant relationship was shown between a decrease in psychopathology and an increase in functionality and increased compliance with treatment.²⁸⁻³⁰ For example, in the 2-year follow-up study by İncedere et al in which the effect of case management on clinical course and medication was evaluated in patients diagnosed with schizophrenia,³⁰ the rate of using medication regularly on his/her own was 6.7% at the first evaluation, and this rate was found to be 56.7% at the end of 24 months.

The GAMA tool is very similar to the 7-point rating used in the study by Kemp et al,²⁴ with a 5-point rating in reverse. In that study, the rating was made by clinical nurses and evaluated as follows: 1, complete refusal to take medication; 2, partial refusal (e.g., refuses depot) or accepts only minimum dose; 3, accepts only because it is compulsory, or very reluctant/requires persuasion, or questions the need often (e.g., once every 2 days); 4, occasional reluctance (e.g., questions the need once a week); 5 passive acceptance; 6, moderate participation, some knowledge and interest in medication, and no prompting required; and 7, active participation, readily accepts, and shows some responsibility for regimen. A rating of 1 on our scale corresponds to 7 in Kemp et al's rating, and a rating of 5 corresponds to 1.

Medication adherence was reported to be related to psychopathology as well as the age at the onset of the illness, comorbid mental illnesses, inadequacy of social support, and problems accessing treatment opportunities.^{4,17,40,41} In our study, while no relationship was found between demographic variables and medication adherence, a significant relationship was found between the age of onset of the illness and adherence to medication (Table 5). Although this correlation is weak, it is a relationship that should be taken into consideration. Horvitz-Lennon et al, in their recent studies, stated that the illness course with early-onset schizophrenia patients has poor long-term outcomes, and one of the important reasons in this case is medication nonadherence.⁴² The researchers found that with timely treatment and medication adherence, hospitalizations and receipt of social beneficiary decreased, and independent/family life improved, and reported that job placement increased. No relationship was found between medication adherence and other demographic and clinical variables in our study. Additionally, it was observed that the presence of comorbidities affected medication adherence at a level

close to significance. Studies show that additional mental and medical diseases accompanying mental disorders negatively affect adherence to medication treatment.^{4,43}

An ideal medication adherence assessment tool should be cost-effective, user-friendly, easy to apply, highly reliable, and practical. However, there is no gold standard assessment tool yet.² For this reason, especially in follow-ups for research purposes, it may be more appropriate to perform a multi-measure evaluation, as emphasized by Lam and Fresco.² In clinical practice, patients often come for treatment with their relatives. Based on the information obtained from them and their relatives, as well as the opinion obtained in the clinical evaluation, the GAMA tool will be a practical measure that should be taken seriously in terms of increasing adherence to medication. During the interview to evaluate compliance with the treatment, the patient's insight will also be assessed spontaneously, and a possible exacerbation will be prevented with the necessary intervention.¹⁷ At the same time, it should not be forgotten to ask the patients not only whether they are taking medications, but also if they have any problems with their medications.³

The study has some limitations. First, the developed scale has not been compared with other treatment compliance scales used in the field. It is a matter of curiosity that comparisons with self-report medication adherence scales will reveal the extent to which patients provide accurate information about treatment compliance and provide information about the reliability of self-report scales. Second, there was no comparison with an objective assessment such as pill count or blood drug levels. However, this method is already expensive and difficult. The most powerful aspect of the scale is that it is so brief and does not require training to use. Additionally, the study has showed the consequences on a large number of patients, including both hospitalized and outpatients.

CONCLUSION

This study showed that the GAMA tool, which evaluates medication adherence in patients with severe mental illnesses, can be used in daily practice. The scale ensures face and convergent validity, and inter-rater reliability. We believe that, as a single-item, 5-point scale, GAMA can take its place as an easily applied assessment tool in clinical studies and research.

Ethics Committee Approval: Ethical permission was obtained from the Kocaeli University Non-invasive Clinical Research Ethics Committee (KÜ GOKAEK 2018/275).

Informed Consent: Written informed consent was obtained from the participants who agreed to take part in the study.

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