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Original Article

Validation and Reliability Assessment of the Test of Adherence to Inhalers (TAI) in Turkish Patients with Chronic Obstructive Pulmonary Disease (COPD)

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ABSTRACT

OBJECTIVE: Accurate assessment of inhaler adherence is essential for optimizing treatment outcomes in patients with chronic obstructive pulmonary disease (COPD). This study aimed to evaluate the validity and reliability of the Turkish version of the Test of Adherence to Inhalers (TAI) in a multicentre COPD cohort.

MATERIAL AND METHODS: A total of 277 patients were included. Sociodemographic characteristics and adherence status [assessed by the Turkish version of the Medication Adherence Report Scale-5 (MARS-5); *İlaç Uyumunu Bildirim Ölçeği* (İUBÖ)] were recorded. Construct validity was evaluated using confirmatory factor analysis (CFA), criterion validity was evaluated by agreement with İUBÖ using kappa statistics, and known-groups validity was evaluated by comparing the number of inhaler devices used. Reliability was assessed using Cronbach's alpha coefficients and item-total correlations.

RESULTS: The mean age was 66.3±8.3 years, 81.9% of participants were male. Most patients (73.6%) used at least two inhaler devices, and 28.9% were classified as non-adherent according to İUBÖ. Based on TAI scores, 43.3% of patients had good adherence, 23.8% had intermediate adherence, and 32.9% had poor adherence. CFA supported the two-factor structure of the TAI (Tucker-Lewis Index: 0.965; Comparative Fit Index: 0.972; Root Mean Square Error of Approximation: 0.114). Criterion validity was demonstrated by good agreement between TAI and İUBÖ (kappa: 0.637, $P < 0.001$). Patients using more than one inhaler device were more likely to be non-adherent according to the TAI-10 ($P = 0.02$). Internal consistency was high for both the 10- and 12-item versions (Cronbach's alpha >0.90), with item-total correlations indicating adequate reliability.

CONCLUSION: The Turkish version of the TAI is a valid and reliable tool for assessing inhaler adherence in patients with COPD and is suitable for both clinical practice and research settings in Türkiye.

KEYWORDS: TAI, medication adherence, COPD, inhaler therapy

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INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is a preventable and treatable non-communicable disease that contributes substantially to global morbidity and mortality. The primary goals in the management of COPD are to reduce symptoms, exacerbations, and hospitalizations, and ultimately to lower the risk of death.[1] Long-term patient adherence to treatment plans plays a crucial role in achieving these outcomes.

However, treatment adherence in chronic diseases is generally low, averaging around 50%,[2] and has been reported to range between 35% and 70% for COPD across different settings.[3-7] A recent observational cross-sectional study of adult COPD patients in Türkiye and Saudi Arabia assessed treatment adherence using the 8-item Morisky Medication Adherence Scale (MMAS-8). The study reported an overall low adherence rate of 49.2%.[8]

Inhalers are the cornerstone of COPD treatment, and both adherence and appropriate inhalation technique play a pivotal role in successful disease management. Currently, there are multiple inhaler devices available, each requiring specific critical steps to ensure adequate drug delivery, which may be confusing for patients.[9]

Several self-report scales, such as the MMAS,[10] the Medication Adherence Report Scale (MARS),[11] and the Test of Adherence to Inhalers (TAI),[12] have been developed to assess medication adherence, and all have been validated for use in COPD. Among these instruments, the MARS can be applied to both oral and inhaled therapies, whereas the TAI was specifically developed for, and validated in, patients using inhaled therapies. Considering the critical importance of medication adherence, we aimed in this study to evaluate the validity and reliability of the Turkish version of the TAI, which is designed to assess inhaler adherence in patients with COPD.

MATERIAL AND METHODS

Study Design and Population

This multicentre cross-sectional study was conducted across various clinical settings in Türkiye. Between June 2021 and June 2022, the electronic medical records of participating centers were screened to identify patients with a diagnosis of COPD, based on the International Classification of Diseases, 10th revision codes J44, J44.0, J44.1, J44.8, and J44.9.

Main Points

- The Turkish version of the Test of Adherence to Inhalers (TAI) demonstrated strong psychometric validity, as evidenced by confirmatory factor analysis and good agreement with an established adherence measure (İUBÖ).
- TAI effectively discriminated between patient groups with different adherence profiles, including those using multiple inhaler devices.
- Internal consistency was high for both the 10-item and 12-item TAI, indicating reliable assessment across both domains.
- The TAI is a practical and reliable tool for evaluating inhaler adherence in Turkish COPD patients, supporting its implementation in clinical practice and future research.

Eligible patients were 40–80 years of age, had been diagnosed with COPD for at least one year, and were receiving at least one COPD maintenance medication [long-acting β_2-agonist (LABA), long-acting muscarinic antagonist (LAMA), inhaled corticosteroid (ICS), LABA/ICS, LAMA/LABA, LAMA + ICS, or triple therapy (LABA/ICS/LAMA)]. Of the 291 eligible patients identified during the screening period, 277 consecutive, clinically stable patients presenting for routine COPD follow-up/diagnostic evaluation, comorbidity management, or other non-exacerbation-related reasons between June and September 2022 were included in the study.

COPD diagnosis was confirmed by spirometry, defined by a post-bronchodilator forced expiratory volume in one second to forced vital capacity ratio <0.7. Exclusion criteria included experiencing an exacerbation within the previous month (because our aim was to assess the psychometric properties of the TAI under stable clinical conditions), inability to understand or speak Turkish sufficiently to comprehend the questionnaires, and cognitive impairment.

The study was approved by the Ankara University Faculty of Medicine Human Research Ethics Committee (approval number: İ11-722-20, date: 05/01/2021)

Data Collection

For all included patients, sociodemographic data (age, sex, educational status, smoking history, and comorbidities) were collected. Disease-related characteristics were systematically assessed, including the severity of dyspnea using the modified Medical Research Council (mMRC) dyspnea scale. Additional information on factors potentially influencing adherence, such as treatment regimens and history of exacerbations, was also recorded.

Adherence Assessment

Medication adherence was evaluated using two validated self-report instruments:

1. The Turkish version of the original MARS-5,[13,14] was validated in Turkish by Temeloğlu-Şen et al.,[15], and titled "*İlaç Uyumunu Bildirim Ölçeği* (İUBÖ)".

2. The Turkish version of the TAI.[12]

Both questionnaires were administered by trained investigators during face-to-face interviews at the participating centers. Before administration, the aim and structure of each questionnaire were carefully explained to participants. Interviews were conducted in a quiet clinical setting to minimize distractions, with each session lasting approximately 15–20 minutes.

Scoring of the Questionnaires

İUBÖ

The İUBÖ comprises five items rated on a 5-point Likert scale (1= always, 5= never), with total scores ranging from 5 to 25. Higher scores indicate better adherence. The five items assess: (1) forgetting to take medication, (2) altering the dose, (3) stopping treatment temporarily, (4) skipping a dose, and (5) taking less than prescribed. Consistent with previous studies, a score of <23 points was considered indicative of non-adherence. The Turkish version of MARS-5 "İUBÖ" has been previously validated and used with permission.

TAI

The TAI is a validated instrument developed to assess the extent to which patients adhere to their prescribed inhaler regimens, particularly in the management of chronic airway diseases such as asthma or COPD. The TAI comprises two complementary components.

The first component, the 10-item TAI, is completed by the patient and designed to determine the overall level of treatment adherence. Each item is rated on a five-point Likert scale ranging from 1 (indicating the lowest level of adherence) to 5 (indicating the highest level of adherence), yielding a total score between 10 and 50. Based on the total score, adherence is classified as good (50 points), intermediate (46–49 points), or poor (≤45 points).

The second component in the 12-item TAI incorporates two additional questions completed by healthcare professionals. These items are scored on a two-point scale: a score of 1 reflects poor knowledge of the treatment regimen and/or the correct inhalation technique, and a score of 2 reflects good knowledge.

When the assessment objective is limited to determining the level of adherence**,** the 10-item version of the TAI is recommended. In contrast, when the aim is to evaluate both the degree of adherence and the underlying patterns of non-compliance**,** the 12-item version should be used. Furthermore, the TAI enables classification of non-compliance behaviors through predefined item groupings**:** items 1–5 assess sporadic non-compliance**,** items 6–10 assess deliberate non-compliance, and items 11–12 assess unconscious non-compliance.

The original version of the TAI, developed by Plaza et al.,[12] was translated and culturally adapted into Turkish in accordance with internationally accepted guidelines for cross-cultural adaptation of patient-reported outcome measures. The process was coordinated by the TAI Scientific Committee in collaboration with Chiesi and the MAPI Research Institute.[16] The adaptation procedure included forward translation by independent bilingual translators, backward translation into the source language, expert panel review, reconciliation of discrepancies, and cognitive debriefing interviews to ensure conceptual equivalence, linguistic accuracy, and cultural appropriateness. Permission to use the Turkish version was obtained from the original developers, and this validated version was used in the present study for validity and reliability analyses.

Statistical Analysis

All statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS) version 25.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics were presented as mean ± standard deviation for normally distributed continuous variables, median (minimum–maximum) for non-normally distributed variables, and frequency (percentage) for categorical variables.

The normality of the data distribution was assessed using the Shapiro–Wilk test and visual methods (histograms and Q–Q plots). For comparisons between groups, the independent samples t-test was used for normally distributed continuous variables, whereas the Mann–Whitney U test was used for non-normally distributed continuous variables. Categorical variables were compared using the chi-square test or Fisher's exact test, as appropriate. A sample-size justification, based on recommendations for CFA (a minimum of 10 participants per item), was applied. With 12 items, the required sample was ≥120; our sample of 277 exceeded this threshold, ensuring adequate power for factor analysis.

The validity was evaluated using construct, criterion, and known-groups validity tests.

Internal Construct Validity: Two-factor confirmatory factor analysis (CFA) for categorical data was performed in MPlus (17) to evaluate the dimensionality of TAI. Factor loadings that were positive or greater than 0.35 were retained in the scale. Tucker-Lewis Index (TLI; >0.90 acceptable, >0.95 excellent), Comparative Fit Index (CFI; >0.90 acceptable, >0.95 excellent), and Root Mean Square Error of Approximation (RMSEA; <0.08 acceptable, <0.05 excellent) were used as goodness-of-fit statistics.[18]

External Construct Validity: Within this scope, the agreement between categorical classifications obtained from the TAI and İUBÖ scales was assessed using Cohen's kappa coefficient (κ). The strength of agreement was interpreted according to Landis and Koch's criteria, where κ values <0.20 indicate slight, 0.21–0.40 fair, 0.41–0.60 moderate, 0.61–0.80 substantial, and >0.80 almost perfect agreement.

Known Groups Validity: The known-groups method evaluates the instrument's ability to distinguish between groups known to differ on a clinically relevant attribute. In the present study, known-groups validity was examined using the chi-square test, based on predefined categories of the number of inhaler devices used. The number of inhalers representing treatment complexity was considered within the known-groups validity framework to assess the discriminatory capacity of the instrument, rather than implying a direct relationship with disease severity.

Reliability: After the internal and external construct validity was confirmed, the reliability was tested for internal consistency using Cronbach's alpha coefficient,[19] with values ≥0.70

considered acceptable and ≥0.80 indicating good reliability. Item-total correlations were calculated to further evaluate internal consistency using Spearman's correlation coefficients. A moderate to strong positive correlation was expected to support criterion validity. All tests were two-tailed, and a *P* value <0.05 was considered statistically significant.

RESULTS

A total of 277 patients from nine different centers (mean age 66.3±8.3 years) were included in the study, of whom 81.9% were male. The overall educational level was low; 61.5% of the patients had only primary or secondary school education. Active smoking was reported by 37.5% of the participants. The median COPD assessment test score was 14 (min: 1, max: 40), and the median mMRC dyspnea scale score was 2 (min: 0, max: 4).

According to the GOLD classification at diagnosis, 44.0% of patients were in stage D and 14.8% were in stage C. According to the 2023 GOLD classification, 58.5% of the patients were categorized as group E, representing the most severe clinical group. The majority of patients (73.6%, n = 204) were prescribed at least two inhaler devices, and 76.5% (n = 212) received at least one additional medication for comorbid conditions other than COPD. Long-term oxygen therapy was used by 30.7% of patients, while 19.5% were on home non-invasive ventilation. Comorbidities were present in 74.0% of the study population. No significant difference was observed in TAI scores across GOLD severity stages.

According to the İUBÖ, 80 patients (28.9%) were classified as non-adherent. Based on the TAI, 120 patients (43.3%) demonstrated good adherence, 66 (23.8%) demonstrated intermediate adherence, and 91 (32.9%) demonstrated poor adherence. Regarding non-compliance patterns, 145 (52.3%) patients exhibited sporadic non-compliance, 105 (37.9%) exhibited deliberate non-compliance, and 100 (36.1%) exhibited unconscious non-compliance.

Validity was assessed using construct, criterion, and known-groups validity tests.

Internal Construct Validity: Following the CFA performed on 12 questions with a 2-factor structure (where patient-completed items and healthcare professional-completed items were analysed separately), the goodness-of-fit statistics were: TLI: 0.965, CFI: 0.972, and RMSEA: 0.114. The factor loadings of the questions on the factors were presented in Table 1.

External Construct Validity: Within the scope of external construct validity, the agreement between the scores obtained from the TAI and those obtained from the İUBÖ scale was evaluated using the κ. The overall agreement was 0.637 ($P < 0.001$) for 10 items, indicating a good level of agreement. The patients classified as non-adherent according to the İUBÖ had lower TAI scores compared with the İUBÖ-adherent group in both domains ($P < 0.001$) (Table 2).

Known-Groups Validity: The majority of patients identified as non-adherent based on the TAI-10 were using more than one inhaler device (n = 59, 64.9%) ($P = 0.02$).

Reliability: It has been tested for internal consistency. The Cronbach's alpha coefficient ranged from 0.913 to 0.925 for the patient domain (Q1-10) and from 0.901 to 0.911 (Q1-12) for the patient/healthcare professional domains (Table 3). Item-total correlations were found ranging from 0.442–0.657 ($P < 0.001$) for patient domain, 0.439–0.644 ($P < 0.001$) for the patient/healthcare professional domains demonstrating a moderate positive correlation that supported criterion validity (Table 4).

DISCUSSION

Medication adherence remains a cornerstone of chronic disease management; however, it continues to be suboptimal, with global estimates indicating that only about half of patients adhere to prescribed treatment regimens.[2] In COPD, adherence to inhaled therapy is particularly critical, as it directly influences symptom control, exacerbation rates, and overall disease progression.[20] Poor adherence is associated with increased healthcare utilization, exacerbations, poorer quality of life, and higher mortality.[3-7,20] Therefore, accurate assessment of inhaler adherence is essential to identify barriers and guide targeted

Table 1. Two-factor confirmatory factor analysis of 12-item Test of Adherence to Inhalers with categorical data

	Factor 1 Patient domain	Factor 2 Healthcare professional domain
Q1	0.868	-
Q2	0.854	-
Q3	0.857	-
Q4	0.901	-
Q5	0.864	-
Q6	0.866	-
Q7	0.910	-
Q8	0.871	-
Q9	0.895	-
Q10	0.801	-
Q11	-	1.205
Q12	-	0.691

Q: Question

Table 2. The relation between Test of Adherence to Inhalers items according to Medication Adherence Report Scale-5

	İUBÖ adherent (n = 197)	İUBÖ non-adherent (n = 80)	*P* value
TAI (Q1–5)	25 (11–25)	19 (9–25)	<0.001
TAI (Q6–10)	25 (15–25)	21.5 (11–25)	<0.001
TAI (Q1–10)	50 (23–50)	38.5 (24–50)	<0.001
TAI (Q1–12)	53 (27–54)	42.5 (26–54)	<0.001

TAI: Test of adherence to inhalers, İUBÖ: *İlaç Uyumunu Bildirim Ölçeği* [Medication Adherence Report Scale-5 (MARS-5)], Q: Question

Table 3. Internal consistency (Cronbach's alpha values) of the Test of Adherence to Inhalers

Patient domain	When item removed	Cronbach alpha for Q (1–5)[a] Q (6–10)[b] Q (11–12)[c]	Cronbach alpha for Q (1–10)	Cronbach alpha for Q (1–12)
Q1–Q5	1	0.865[a]	0.917	0.904
	2	0.863[a]	0.919	0.907
	3	0.856[a]	0.918	0.906
	4	0.847[a]	0.913	0.901
	5	0.872[a]	0.915	0.903
Q6–Q10	6	0.860[b]	0.916	0.903
	7	0.833[b]	0.915	0.902
	8	0.867[b]	0.916	0.902
	9	0.846[b]	0.917	0.904
	10	0.886[b]	0.925	0.911
Healthcare professional domain				
Q11–Q12	11	0.912[c]	-	0.916
	12	0.769[c]	-	0.921

Q: Question

Table 4. Item total score correlation for the Test of Adherence to Inhalers

		Q (1–5)[a]/Q (6–10)[b]		Q (1–10)		Q (1–12)	
Patient domain	Q	r	*P*	r	*P*	r	*P*
Q1–Q5	1	0.701[a]	<0.001	0.450	<0.001	0.480	<0.001
	2	0.832[a]	<0.001	0.564	<0.001	0.556	<0.001
	3	0.824[a]	<0.001	0.657	<0.001	0.644	<0.001
	4	0.775[a]	<0.001	0.620	<0.001	0.606	<0.001
	5	0.702[a]	<0.001	0.626	<0.001	0.615	<0.001
Q6–Q10	6	0.795[b]	<0.001	0.617	<0.001	0.609	<0.001
	7	0.827[b]	<0.001	0.608	<0.001	0.607	<0.001
	8	0.858[b]	<0.001	0.607	<0.001	0.616	<0.001
	9	0.796[b]	<0.001	0.592	<0.001	0.587	<0.001
	10	0.606[b]	<0.001	0.442	<0.001	0.439	<0.001
Healthcare professional domain							
Q11–12	11			0.262	<0.001	0.369	<0.001
	12			0.085	0.156	0.304	<0.001

Q: Question

interventions. In this context, the present study evaluated the validity and reliability of the Turkish version of the TAI and demonstrated that it has robust psychometric properties in patients with COPD. CFA supported the original two-factor structure; criterion validity showed substantial agreement with the validated İUBÖ (κ: 0.637); and internal consistency was excellent (Cronbach's alpha >0.90). Additionally, the instrument demonstrated adequate discriminatory capacity in known-groups analysis.

The validity was evaluated by construct, criterion, and known-groups validity tests. The construct validity of the Turkish version of the TAI was confirmed by CFA, which demonstrated an acceptable model fit with two underlying domains: the patient-completed items (questions 1–10) and the healthcare professional-completed items (questions 11–12). This structure aligns with the original version developed by Plaza et al.[12] and has been replicated in several cross-cultural validations, including studies from Spain, China, Iran, Malaysia, and most recently, Taiwan.[21-25] The goodness-of-fit indices in our analysis (TLI: 0.965, CFI: 0.972, RMSEA: 0.114) were consistent with or superior to those reported in previous validations (RMSEA range 0.07–0.12), supporting the construct validity of the instrument.

Criterion validity was evaluated by comparing TAI and İUBÖ scores, which demonstrated a good level of agreement (κ: 0.637, $P < 0.001$). These findings are consistent with earlier reports showing modest correlations between self-reported adherence scales and electronic monitoring or pharmacy refill data.[12,21] Such moderate associations are expected since self-report tools capture the behavioural dimensions of adherence,

whereas electronic or pharmacologic metrics assess dose-based adherence. A 2024 systematic review and meta-analysis by Vauterin et al.[20] reinforced that patient-reported measures remain valuable in clinical practice, especially when used alongside objective adherence monitoring to understand non-adherence subtypes.

Known-groups validity analysis in this study demonstrated that the majority of patients identified as non-adherent based on the TAI-10 were using more than one inhaler device, suggesting that increasing treatment complexity may adversely affect adherence. This finding is consistent with the comprehensive review by Usmani et al.,[26] which included 114 articles and reported that simplifying inhaler regimens—particularly by using the same type of device for concomitant inhaled medications—minimizes device-related errors, improves adherence, and enhances clinical outcomes. Similarly, in another study, multivariable analysis showed that the use of multiple inhaler devices (adjusted odds ratio: 11.68; 95% confidence interval: 3.29–41.51) were independently associated with an increased likelihood of making critical inhaler technique errors.[27] Different inhaler types (e.g., dry powder inhaler, metered-dose inhaler, soft-mist inhalers) may also independently affect usability and adherence. However, stratified or multivariable analyses by inhaler device type were not prespecified within the study's psychometric validation framework. This limitation has now been explicitly acknowledged.

Regarding reliability, the internal consistency of the Turkish TAI was excellent: Cronbach's alpha coefficients exceeded 0.9 for both the 10-item and 12-item TAI, surpassing the acceptable reliability threshold. Item-total correlations were at least moderately positive, confirming homogeneity among items. These findings are in line with previous psychometric evaluations, which reported Cronbach's alpha values of 0.843 in China,[22] 0.873 in Spain,[21] 0.986 in Iran,[23] 0.823 in Malaysia,[24] and 0.82 in Taiwan.[25] This consistency across different cultures shows that the TAI is a reliable and standardized tool for measuring inhaler adherence.

Study Limitations

Despite these findings, this study has some limitations. First, its cross-sectional design does not allow conclusions about causality. Second, adherence was measured using self-report questionnaires, which may lead to reporting bias. Third, most participating centers were tertiary referral hospitals, which may have resulted in a higher proportion of severe COPD cases and may have limited the generalizability of the results. Finally, although exploratory analyses were conducted, the effects of treatment complexity and inhaler device type cannot be completely ruled out.

CONCLUSION

This multicenter study demonstrates that the Turkish version of the TAI is a valid and reliable instrument for assessing inhaler adherence in patients with COPD. The tool showed strong internal consistency, a supported factor structure, and substantial agreement with an established adherence scale. Its implementation may facilitate standardized assessment of inhaler adherence in both clinical practice and research settings in Türkiye.

Ethics

Ethics Committee Approval: The study was approved by the Ankara University Faculty of Medicine Human Research Ethics Committee (approval number: İ11-722-20, date: 05/01/2021)

Informed Consent: Consent forms are obtained from all patients.

Footnotes

Authorship Contributions

Surgical and Medical Practices: S.Y., E.S.Ö., D.P.Y., A.M.Ş., E.S., N.K., A.M., Y.V., A.B., F.E., İ.Ç.C., Concept: A.Ö.A., E.Ş., S.A.N., D.P.Y., N.K., A.B., A.G., İ.Ç.C., M.P., İ.Ş., G.U., O.Y.T., A.K., Design: A.Ö.A., E.Ş., A.B., Data Collection or Processing: A.Ö.A., E.Ş., S.Y., D.G., S.A.N., E.S.Ö., D.P.Y., A.M.Ş., E.S., N.K., A.M., Y.V., F.E., A.G., İ.Ç.C., Analysis or Interpretation: A.Ö.A., D.G., Literature Search: A.Ö.A., İ.Ç.C., M.P., İ.Ş., G.U., O.Y.T., A.K., Writing: A.Ö.A.

Conflict of Interest: Aylin Özgen Alpaydın, MD, and İpek Çaylı Candemir, MD, are Editors of Thoracic Research and Practice. They were not involved in the peer-review process of this article and had no access to any information regarding its peer review. Nurdan Köktürk, MD, is a member Editorial Board of Thoracic Research and Practice. She was not involved in the peer-review process of this article and had no access to any information regarding its peer review. The other authors declare no conflicts of interest.

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Declaration of AI Use: During the preparation of this work, the author(s) utilized OpenAI's ChatGPT to review the language of the manuscript. After carefully reviewing and editing the content as necessary, full responsibility for the publication's content is taken by the author(s). This incorporation of AI tool usage primarily impacted the editing of the manuscript.

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