

Determinants of Inhaler Adherence in COPD and Asthma Patients: An Interim National Study from Albania

Irina Argjiri^{1,2*}, Klejda Harasani², Dhimitraq Argjiri³, Ejsi Vula⁴

¹ Ministry of Health and Social Protection, Tirana, Albania

² Department of Pharmacy, University of Medicine, Tirana; Tirana, Albania

³ Tirana Regional Hospital Centre “Shefqet Ndroqi”, Tirana, Albania

⁴ University Hospital Center "Mother Teresa", Tirana, Albania

Abstract

Background: Adherence to inhaled therapy is essential for managing Chronic Obstructive Pulmonary Disease (COPD) and asthma, yet no real-world adherence data exist for Albanian patients.

Aims: The aim of this study is to evaluate inhaler adherence patterns and determinants among Albanian Chronic Obstructive Pulmonary Disease (COPD) and asthma patients using the Test of Adherence to Inhalers (TAI).

Study design: A cross-sectional study with a 12-month prospective recruitment period was conducted at the Tirana Regional Hospital Centre “Shefqet Ndroqi” (March 2024 – March 2025). The analysis presented is an interim snapshot, presenting data collected until January 2025.

Methods: Based on statistical calculations, 236 patients were targeted. The TAI-12 questionnaire was adapted and translated into Albanian. Adherence was analyzed using GraphPad Prism, using ANOVA and paired/unpaired t-tests.

Results: Of 148 patients, 92.6 % were non-adherent, with only 2.7 % adherent but unconscious non-compliant. Mean score was 35.30 (SD 5.29) for Q1–10 and 2.86 (SD 0.78) for Q11–12. Self-report exceeded provider rating ($p < 0.0001$). Higher education level and age < 50 years were associated with better provider-rated adherence ($p = 0.001$ and $p < 0.0001$, respectively). Q11-12 scores were also higher in asthma patients ($p = 0.0102$) compared to COPD.

Multi-provider instruction correlated with higher self-reported adherence ($p = 0.0417$).

Conclusion: Most Albanian patients overestimate adherence. However, education level positively influenced objective adherence, while multidisciplinary instruction improved self-reported adherence. Therefore, structured national programs and coordinated care by multiple providers are needed to improve disease management.

Keywords: Medication Adherence, Inhalation Therapy, Asthma, Chronic Obstructive Pulmonary Disease (COPD)

1. INTRODUCTION

Adherence to inhaled therapy is critical for the management of Chronic Obstructive Pulmonary Disease (COPD) and asthma. Despite effective treatments, poor adherence remains a common cause for adverse clinical and economic outcomes. No real-world data regarding inhaler adherence exist for Albanian populations, creating a major barrier for the development of targeted interventions.

The Test of Adherence to Inhalers (TAI) was developed and validated to provide a standardized tool to measure adherence in patients with asthma and COPD (1). First adapted into Spanish, and afterwards into multiple languages, including Italian, Chinese, and Malay (2-4), TAI has shown good psychometric properties across different populations and healthcare systems. Recent validations in Taiwan (5) and other Asian settings further confirm its cross-cultural robustness.

Compared to other adherence questionnaires, the TAI combines patient self-report (Q1 – 10) with healthcare provider assessment (Q11 – 12), providing information on both behavioral patterns and correct inhaler technique. This dual perspective is critical, as data suggest that patients often overestimate their self-reported adherence (6), which can lead to clinical inertia and delayed therapeutic changes. Reviews comparing available adherence tools confirm that the TAI remains one of the most specific and context-sensitive instruments to measure inhaler adherence (7,8).

There has not been any systematic study of inhaler adherence using validated tools in Albania. The present study aims to fill this gap by analyzing adherence patterns among Albanian patients with COPD and asthma using the TAI questionnaire and identifying sociodemographic and clinical factors that affect the level of adherence. Findings from this study will offer one of the first structured evidence on adherence behaviors in Albania, and help guide future health policy and professional training programs.

2. MATERIAL AND METHODS

2.1. Study Design and Setting

The study design is a cross-sectional survey conducted within a 12-month prospective recruitment period (March 2024–March 2025) at the Tirana Regional Hospital Centre “Shefqet Ndroqi”, the national referral centre for pulmonary diseases in Albania. The analysis presented is an interim snapshot, presenting data collected until January 2025.

2.2. Study Population

All patients with a previously confirmed diagnosis of asthma or COPD who presented to the Tirana Regional Hospital Centre “Shefqet Ndroqi” during the study period were eligible for inclusion. Diagnoses were verified from existing medical records and spirometry-confirmed airflow limitation, following the Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria for COPD (9) and the Global Initiative for Asthma (GINA) criteria for asthma (10).

To ensure the accuracy of self-reported data, exclusion criteria included patients with documented cognitive impairment, those unable to provide informed consent (including illiterate patients without a witness), and patients who had experienced an acute exacerbation of COPD or asthma within the 14 days preceding the interview.

Sample size was assessed using an online sample size calculator (11) for a predetermined population of 608 hospitalized COPD and asthma patients, using the data from the Statistics Department of the Hospital for the year 2023. With a confidence level of 95 %, a percentage margin of error ± 5 %, and a conservative expected proportion of 50 %, the minimum sample size obtained was 236 patients. This interim analysis includes 148 patients.

2.3. TAI Translation and Pilot Testing

The TAI-12 questionnaire underwent a formal linguistic and cultural adaptation, including forward/ back translation by two independent bilingual experts (E.V. and K.H.), reviewing by a pharmacist and a physician (I.A. and Dh.A.), and pilot-testing on five healthcare professionals for clarity of questions and ease of administration.

2.4. Data Collection

Data was collected by individual patient interviews and clinical assessments performed by trained pulmonologists and medical residents. All assessors had been previously trained on the standardized administration of the questionnaire and adherence assessment procedures to ensure consistency and reduce variability.

The TAI-12 consists of:

- *Part 1 (Q1–10)* – self-administered patient section on adherence behaviors, each scored 1–5 (range 10 – 50).
- *Part 2 (Q11–12)* – clinician-administered assessment of inhaler technique and regimen knowledge, each scored 1 – 2 (range 2 – 4).

The total score ranges from 10 to 54: adherence (50 – 54), intermediate adherence (46 – 49), and non-adherence (< 45).

Patient information was collected regarding demographics (age, gender, residence, and education), diagnosis and disease severity (categorized according to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) classification), type and number of inhalers used, duration after diagnosis in years (for those diagnosed before the survey), and from whom patients had learned inhaler technique when available (pulmonologist, General Practitioner, pharmacist, or multiple providers).

The full translated TAI-12 questionnaire in Albanian is provided in Appendix A.

2.5. Statistical Analysis

Analysis was performed using GraphPad Prism. Paired t-tests compared Q1-10 and Q11-12 scores. One-way ANOVA and unpaired t-tests examined differences across demographic and clinical categories. We considered $p < 0.05$ as statistically significant.

2.6. Ethics

The study protocol was approved by the Ethics Committee of the University of Medicine, Tirana

(approval number 2096/1 Prot., dated 01.08.2024). All participants were provided with standardized informed consent form prior to enrollment. The form included two sections: an information sheet outlining the study objectives, procedures, benefits, risks, and confidentiality measures, and a consent certificate signed by the participant. All participants provided written informed consent or were fingerprinted in the presence of a literate witness.

3. RESULTS

3.1. Participant characteristics

Of the 148 enrolled patients, the mean age was 64.9 years ($\pm$ 12.4); with 106 (71.6 %) male

participants. 54.1 % of the sample were urban residents, and 62.2 % had higher education. COPD was diagnosed in 54.7 % and asthma in 45.3 % of patients, respectively. Average FEV₁ was 61.3 % (range: 15 – 120.3 %).

Most patients (62.2 %) received inhaler instruction from multiple providers, while only 37.8 % were instructed by a single provider. Nearly all patients used two or more inhalers. In 48.6 % of cases, disease duration was longer than 5 years.

Demographic data are summarized in Table 1.

3.2 Adherence outcomes

Table 1. Demographic and clinical characteristics of the study participants (N = 148)

Characteristic	Value
Age, mean (SD)	64.9 years ($\pm$ 12.4)
Gender, n (%)	Male: 106 (71.6 %) Female: 42 (28.4 %)
Place of residence, n (%)	Urban: 80 (54.1 %) Rural: 68 (45.9 %)
Education level, n (%)	High: 92 (62.2 %) Secondary: 21 (14.2 %) Low: 35 (23.6 %)
Diagnosis, n (%)	Asthma: 67 (45.3 %) COPD: 81 (54.7 %)
FEV ₁ (%), mean (range)	61.3 % (15–120.3 %)
Instruction on inhaler use, n (%)	One provider (pulmonologist/pharmacist): 56 (37.8 %) Multiple providers: 92 (62.2 %)
Number of inhalers used, n (%)	One: 24 (16.2 %) Two: 71 (48.0 %) Three or more: 53 (35.8 %)

Profession, n (%)	Farmer: 56 (37.8 %)
	Manual worker: 72 (48.6 %)
	Office worker: 15 (10.1 %)
	Student: 3 (2.0 %)
	Housewife: 2 (1.4 %)
Years since diagnosis, n (%)	1–3 years: 35 (23.6 %)
	3–5 years: 42 (28.4 %)
	5–10 years: 40 (27.0 %)
	>10 years: 31 (20.9 %)

COPD = Chronic Obstructive Pulmonary Disease; FEV₁ = forced expiratory volume in 1 second; SD = standard deviation. Values are presented as mean ($\pm$ SD), range, or number (percentage), as appropriate.

More than 9 out of 10 patients (92.6 %) were classified as non-adherent, with intermediate adherence in 4.7 % and good adherence in 2.7 % (with unintentional non-compliance).

The mean score for questions 1 to 10 (Q1-10) was 35.30 (SD = 5.29), and for questions 11 and 12 (Q11-12) was 2.86 (SD = 0.78), with significant overestimated self-reported adherence (mean difference = 32.44; 95 % CI: 31.58 to 33.30; $p < 0.0001$).

Subgroup analyses showed that asthma patients ($n = 67$) had significantly higher Q11-12 scores compared to COPD patients ($n = 81$, mean difference = 0.33; 95% CI: 0.08 to 0.58; $p = 0.0102$) (Figure 1). No significant differences were found by gender, disease duration, or place of residence.

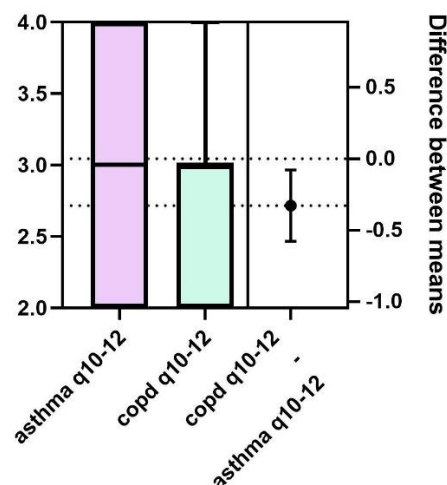


Figure 1. Provider-rated adherence scores (Q11–12) in asthma patients (purple) and COPD patients (green), interim analysis, N=148

Education level was not associated with self-reported adherence; however, it was positively associated with provider-rated adherence (mean difference = 0.46; 95% CI: 0.19 to 0.73; $p = 0.001$) (Figure 2).

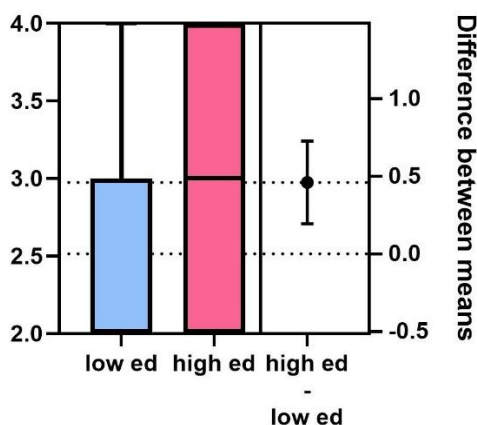


Figure 2. Provider-rated adherence scores (Q11–12) by education level, interim analysis, N=148

Patients under 50 years old had higher Q11–12 scores compared to older patients ($p < 0.0001$). Post-hoc Tukey's comparisons showed that patients aged <50 years had higher adherence scores than those aged 50–75 years (mean difference = 0.93; 95% CI: 0.53 to 1.34; $p < 0.0001$) and those >75 years (mean difference = 1.59; 95% CI: 1.12 to 2.06; $p < 0.0001$), while the 50–75 age group also scored higher than the >75 group (mean difference = 0.66; 95% CI: 0.34 to 0.98; $p < 0.0001$) (Figure 3). Multi-provider instruction was associated with higher Q1–10 scores (mean difference = 1.83; 95% CI: 0.07 to 3.59; $p = 0.0417$) (Figure 4).

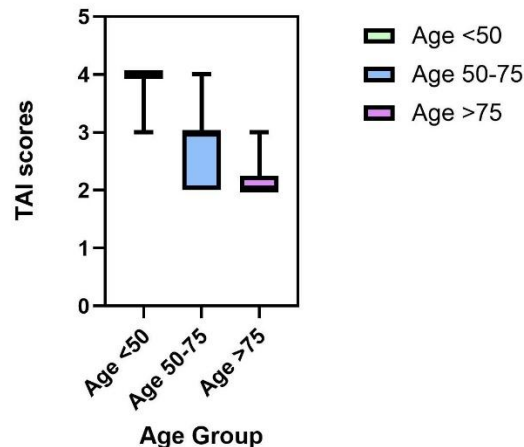


Figure 3. Provider-rated adherence scores (Q11–12) by age group, interim analysis, N=148

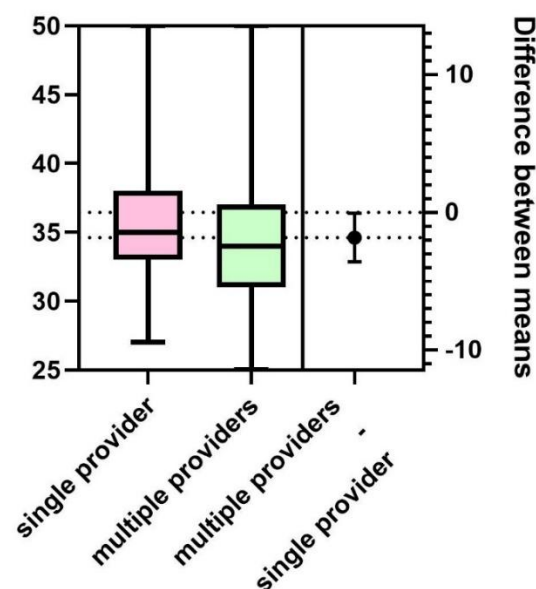


Figure 4. Self-reported adherence scores (Q1–10) by number of healthcare providers counseling patients, interim analysis, N=148

To address potential confounding, stratified multivariable linear regression models were performed for the Asthma (N=67) and COPD (N=81) cohorts. In the Asthma group, younger age ($p=0.014$) and lower education ($p=0.044$) were identified as independent predictors of total

TAI scores ($R^2=0.460$) (Table 2). For the COPD group, occupation ($p=0.009$) and disease duration ($p=0.045$) significantly influenced adherence,

whereas FEV1 % and COPD Stage did not independently predict scores in this interim sample (Table 3).

Table 2. Linear regression for Asthma patients, N= 67

Model Fit Measures

Model	R	R ²	Overall Model Test			
			F	df1	df2	p
1	0.678	0.460	2.27	18	48	0.012

Note. Models estimated using sample size of N=67

Model Coefficients - Total TAI 1-12

Predictor	Estimate	SE	t	p
Intercept ^a	43.2132	8.7258	4.95235	<.001
AGE	-0.1462	0.0571	-2.56219	0.014
FEV1, %	0.0505	0.0808	0.62477	0.535
NUMBER OF INHALERS	-1.4779	1.7271	-0.85572	0.396
GENDER:				
1 MALE – 0 FEMALE	-0.2704	1.4853	-0.18206	0.856
RESIDENCE:				
2 SUBURBS – 1 CITY	-0.3118	2.3246	-0.13412	0.894
OCCUPATION:				
2 - MANUAL WORKER – 1- FARMER	2.3692	2.2483	1.05378	0.297
3- ADMINISTRATE WORKER – 1- FARMER	6.8645	3.2712	2.09849	0.041
4 STUDENT – 1- FARMER	-4.6310	4.3279	-1.07002	0.290
5 UNEMPLOYED – 1- FARMER	-3.1953	4.5776	-0.69803	0.489
EDUCATION:				
2- HIGH – 1- MIDDLE	0.0242	2.5269	0.00958	0.992
3- LOW – 1- MIDDLE	4.2430	2.0536	2.06616	0.044
4 – 1- MIDDLE	2.6400	5.9843	0.44116	0.661

ASTHMA:

2 – 1	2.3213	2.4087	0.96371	0.340
3 – 1	7.7705	4.1673	1.86463	0.068

YEARS SICK:

2 (3-5) – 1 (1-3)	-1.4382	2.3000	- 0.62530	0.535
3 (5-10) – 1 (1-3)	0.3109	2.2299	0.13942	0.890
4 (>10) – 1 (1-3)	2.9989	2.5941	1.15603	0.253

TRAINING:

2 MULTIPLE PROVIDER – 1 SINGLE PROVIDER	-3.0100	1.6703	- 1.80202	0.078
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^a Represents reference level

Table 3. Linear regression for COPD patients, N= 81

Model Fit Measures

Model	R	R ²	Overall Model Test			
			F	df1	df2	p
1	0.557	0.310	1.67	17	63	0.074

Note. Models estimated using sample size of N=81

Model Coefficients - Total TAI 1-12

Predictor	Estimate	SE	t	p
Intercept ^a	39.3595	8.8680	4.438	<.001
AGE	-0.0326	0.0759	-0.429	0.669
FEV1, %	-0.0700	0.0503	-1.391	0.169
NUMBER OF INHALERS	2.2222	1.8296	1.215	0.229
GENDER:				
1 MALE – 0 FEMALE	7.7369	4.8529	1.594	0.116
RESIDENCE:				
2 SUBURBS – 1 CITY	-1.7100	1.3328	-1.283	0.204

OCCUPATION:

2 - MANUAL WORKER – 1- FARMER	-1.8930	1.4290	-1.325	0.190
3- ADMINISTRATE WORKER – 1- FARMER	-2.5973	2.8440	-0.913	0.365
4 STUDENT – 1- FARMER	14.1242	5.2669	2.682	0.009

EDUCATION:

2- HIGH – 1- MIDDLE	2.7097	2.2255	1.218	0.228
3- LOW – 1- MIDDLE	0.5400	1.6276	0.332	0.741
4 – 1- MIDDLE	0.8989	2.2585	0.398	0.692

COPD stage:

2 B – 1 A	-4.6337	3.3133	-1.399	0.167
3 C – 1 A	-5.1530	4.7519	-1.084	0.282

YEARS SICK:

2 (3-5) – 1 (1-3)	-0.6731	1.4651	-0.459	0.648
3 (5-10) – 1 (1-3)	-0.3056	1.7493	-0.175	0.862
4 (>10) – 1 (1-3)	-3.4514	1.8430	-1.873	0.066

TRAINING:

2 MULTIPLE PROVIDER – 1 SINGLE PROVIDER	-1.9189	1.2188	-1.574	0.120
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^a Represents reference level

4. DISCUSSION

To our knowledge, this is the first systematic evaluation of compliance with inhaler treatment for COPD and asthma patients in Albania, presenting a preliminary validation of a combined self-reported physicians' evaluation tool.

Our results are in line with global studies and indicate a critical gap between perceived and actual adherence among Albanian patients using inhalers (6,12,13). The findings of this interim analysis reveal a strikingly low rate of good adherence (2.7%). This figure represents the subset of patients who demonstrated both high behavioural intent and perfect technical execution of their inhaler regimen. While this percentage may appear low, it is consistent with objective global studies from other populations (14-18) where patient-reported adherence often exceeds objective measures by 30 – 90 %. This bias highlights why self-report alone is insufficient when making clinical decisions.

Our multivariable analysis provides the mathematical justification for this result by revealing a significant 'technical-behavioural gap'. While factors such as education and occupation influenced what patients *reported* (Q1–10), the objective physical technique (Q11–12) was driven almost exclusively by age-related barriers ($p < 0.001$ for both cohorts). This divergence provides the empirical proof for the “unconscious non-compliance” classification established in the official TAI User Guide. This category identifies patients who believe they are 100% adherent based on their routine (Q1–10),

but are in fact non-adherent due to technical failures (Q11–12) that they are unaware of.

Furthermore, the identification of “adherence fatigue” in our COPD cohort, where patients sick for over 10 years showed significantly lower adherence than those in the 1 to 3-year group ($p = 0.045$), suggests that the 2.7% adherence group likely consists of younger, more recently diagnosed patients who have not yet reached the point of technical complacency or behavioural fatigue. This underscores the critical need for repeated, clinician-led technical evaluations rather than relying on patient perception alone.

Education appeared to influence actual adherence (provider-rated) but not perceived adherence. This suggests that higher health literacy may improve inhaler technique and regimen compliance, as supported by Poureslami et al. (2022) (19).

These data support the well-acknowledged limitation of using self-report measures as the sole evaluative way to assess adherence. Even in a largely non-adherent patient population, a significant number of patients believed that they were adherent, which underscores the importance of objective or clinician-administered tools to detect and correct these biases.

Patients who were instructed by multiple providers described a higher level of adherence to the instructions, which in turn underscores the importance of multimodal care. Previous studies (14,20) show that coordinated input from pulmonologists and pharmacists improves both inhaler use and clinical outcomes. It is important

to note that, while other studies have indeed documented an association with male gender and shorter disease duration (21,22), the effect of these factors was not significant in our cohort. These findings may indicate varying healthcare delivery, patient education systems, or cultural beliefs regarding the treatment and management of chronic diseases; further supporting individualized adherence interventions in Albania rather than broad generalizations based on demographics.

Strengths of our study include the use of a validated, dual-perspective adherence tool, structured data collection by trained staff, and a diverse sample.

Limitations include the single-center setting, the interim nature of the analysis, and the cross-sectional design, which may cause causal inference.

5. CONCLUSION

These interim findings suggest that while Albanian patients may report high adherence intent, objective technical errors remain the dominant barrier to effective therapy. Future analysis of the full national dataset will further refine these associations and guide targeted respiratory policy in Albania.

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Conflict of Interest: The authors declare no financial or non-financial conflicts of interest related to this work.

Ethical approval: The study protocol was approved by the Ethics Committee of the University of Medicine, Tirana (approval number 2096/1 Prot., dated 01.08.2024).

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