Patient Preference and Adherence

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ORIGINAL RESEARCH

Validation of Basque "Test of Adherence to Inhalers" in Asthma and Chronic Obstructive Pulmonary Disease

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Purpose: To adapt the Test of Adherence to Inhalers (TAI) questionnaire to Basque language and evaluate the psychometric properties.

Patients and Methods: A cross-sectional observational study was carried out. We recruited Basque-speaking adults aged ≥18 years who attended the respiratory outpatient clinics in the last 5 years for follow-up with a diagnosis of asthma (n=249) or chronic obstructive pulmonary disease (COPD) (n=149). Patients were contacted by postal mail and reminders were sent to non-respondents. The TAI was translated into Basque and back-translated into Spanish. The comprehensibility and feasibility of Basque TAI were evaluated through cognitive debriefing interviews. We performed the descriptive of the questionnaire and assessed reliability by Cronbach's alpha, structure validity by confirmatory factor analysis (CFA) and known-groups validity by Wilcoxon and Kruskal–Wallis tests according to disease severity, exacerbations and Charlson Comorbidity Index (CCI).

Results: Mean TAI score were 44.82 (standard deviation (SD)=7.26) and 48.52 (SD=3.88) for patients with asthma and COPD, respectively. No floor effect was observed in any cohort. 38.14% of patients with asthma and 67.21% with COPD reported good adherence (maximum score), indicating a ceiling effect. The Cronbach's alphas were 0.881 and 0.836 for the asthma and COPD cohorts, respectively, demonstrating adequate reliability. In the CFA, each item loading was >0.4, suggesting that they fit into a single dimension. Mean TAI score was higher in patients with asthma experiencing exacerbations ($p<0.05$) and more severe asthma and COPD ($p<0.0001$) as compared to their counterparts, which demonstrates the known-groups validity. TAI score did not differ according to comorbidities.

Conclusion: The Basque TAI is valid, reliable and useful for measuring adherence to inhalers in patients with asthma and COPD in clinical and research settings.

Keywords: psychometrics, validity, reliability, TAI questionnaire, asthma, COPD, PROM

Introduction

Asthma and chronic obstructive pulmonary disease (COPD) are common conditions characterized by chronic airway and/or lung disease. [1,2] Asthma affects the 1–29% of the population worldwide, including children, and the global prevalence of COPD is estimated to be 10%. As determined by major global guidelines, inhaled medicines are the recommended pharmacological drugs to treat both disorders, including relievers (eg, short- and long-acting beta-2 agonists, LABAs), preventers/controller medications (eg, inhaled corticosteroids, ICS), long acting muscarinic antagonists (LAMAs), and combination inhalers (eg, LAMA/LABA). [1,2]

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Appropriate adherence to inhaled therapy is crucial for the management of asthma and COPD, improvement of clinical outcomes and subsequent reduction of treatment costs.[3,4] Indeed, lack of adherence to prescribed recommendations is associated with poorer lung function, increased risk of exacerbations, hospital admissions and risk of death in patients with COPD and asthma. Nevertheless, adherence to inhalators are under desirable levels in asthma and COPD.[3,4] That is why, clinical guidelines in asthma and COPD highlight the needing of actively determine and solve the non-compliance.[5,6] In contrast to objective direct measures, indirect methods like patient-reported outcome measures (PROMs) offer an easy, cost-effective way to evaluate the adherence in clinical practice.[7] Despite their potential limitations, including the assessment of the validity, there are several questionnaires that assess the adherence to medication.[8] Due to its proper psychometric properties, practical accessibility and usability in clinical settings, the Test of Adherence to Inhalers (TAI) is recognized as one of the best available PROM.[9,10] Differing from the other tools, TAI was designed for evaluation of the specific adherence to inhaled therapy in asthma and COPD and it was exhaustively co-developed by a multidisciplinary team of health care professionals and patients in Spain.[9] In addition, TAI not only allows the identification of the adherence level, but also detects the behavior patterns of non-adherence associated to barriers, which is a key issue to elaborate personalized education strategies. Indeed, its value has been enhanced by the recent development of the TAI Toolkit, which offers a guidance on how to manage the non-adherence patterns with adherence-promoting interventions.[11,12] Regarding the application of TAI in the research area, patients suffering from COPD usually report higher adherence level than the asthmatic ones.[13–15] In addition, TAI-measured adherence has been related to several social and clinical factors including educational level, patient knowledge and perceptions of the asthma and COPD, disease severity and comorbidities.[16–20]

Considering related works, there is strong evidence about the validity and reliability of the original Spanish version, in which the psychometric characteristics have been partially and fully evaluated.[9,21] Other transcultural adaptations to own languages in China, Iran and Malaysia have also been demonstrated to be valid and reliable in patients with asthma and COPD treated with inhalators, adding scientific proofs to the usefulness of TAI.[22–24]

The Spanish version of the TAI is frequently used in healthcare practice in the pneumology area of Osakidetza, the Public Health System in the Basque Country, Autonomous Community of Spain. However, there is no suitable version of TAI for Basque. Basque is a co-official bilingual language in Basque Country and is widely used in the surrounding areas the Autonomous Community of Navarra and southern France.[25,26] As required by the politics of Osakidetza and the Basque Government, we adapted the TAI to the Basque language.[27–29] To ascertain the quality requirements of the measurement instruments, adaptation was performed following the International Quality of Life Assessment (IQOLA) and cognitive interviews.[30–34]

This study aimed to evaluate the psychometric properties of the Basque 10-item TAI, including reliability and construct validity, using both structure and known-groups validity.

Material and Methods

Participants

The study was conducted at Galdakao-Usansolo University Hospital, a hospital that belongs to the Basque Health Public Service called Osakidetza in Basque Autonomous Country, Spain. Eligible patients were Basque speaking adults aged ≥18 years who attended the Respiratory Service outpatient clinics in the last 5 years for follow-up of asthma or COPD diagnosis defined by the Global Initiative for Chronic Obstructive Pulmonary Disease (GOLD) and the Spanish Guidelines for the Management of Asthma (GEMA).[1,35] Exclusion criteria were end of life situation, inappropriate expected completion of the questionnaire due to severe psychiatric problems, neurosensory or other health issues, and unsigned informed consent form. Recruitment was conducted between March, 2021 and February, 2022.

The project was approved by the ethics committee of the Barrualde-Galdakao Integrated Health Organization (Protocol number 25/20), who manages the hospital where this work was performed and who belongs to Osakidetza. It certified that the study complies with the principles of the Declaration of Helsinki.

TAI Questionnaire

It is a questionnaire specifically aimed at measuring adherence to inhalers in patients with asthma or COPD in a simple and reliable manner.[9] It consists of 12 items. The first 10 items (named 10-item TAI) must be completed by the patient and each item has 5 response options scored from 1 (worst therapeutic adherence) to 5 (best therapeutic adherence). Then, the scores are summed up so that the adherence level can be established as good (total score=50), intermediate (total score between 46–49) or poor (total score ≤45). The two additional items must be answered by a health professional and classify as poor (1 point) or good (2 points) the knowledge of the treatment regimen (item #11) and technique (item #12). The 12-item TAI questionnaire provides guidance on the types of patient non-compliance patterns. It can be erratic (total score of 5 to 25 on items #1 to #5), referring to forgetfulness to take medication; deliberate (total score of 5 to 25 on items #6 to #10), referring to patient's decision not to take the medication; or unwitting (total score of <4 on items #11 and #12), referring to not taking inhalers due to ignorance of the treatment regimen or technique. It is a questionnaire originally developed in Spanish and its validity and reliability have been demonstrated.[9] The TAI questionnaire belongs to CHIESI ESPAÑA S.A.U. and was created by the Scientific Committee of the TAI Project.

Procedure

First, permission was obtained from Chiesi España S.A.U. The TAI questionnaire was translated and back-translated following the IQOLA method.[32,33] In short, it was translated from Spanish to Basque by two independent certified bilingual Basque mother language translators. Those translations were reviewed and consolidated so the first Basque version was obtained. It was then back-translated into Spanish by two other bilingual Spanish mother language translators, also independently certified. A consensus back-translation was made, used to compare with the source and develop the second Basque version. Then, cognitive interviews with patients and clinicians were conducted to test the comprehensibility and feasibility of administering the questionnaire.[34] Among all who met the inclusion criteria, patients were selected by random sampling, recruited by phone and arranged for an interview. Modifications and comments suggested were considered to generate the final Basque version. Each Basque version had the approval of the professional translators, the research group, including researchers and clinicians, and Chiesi España S.A.U.

Next, the psychometric properties of the final Basque version were evaluated in a cross-sectional observational study. Sample size was calculated based on the structure validity study, following the criterion of 20 individuals per item, as described elsewhere.[36,37] Among patients who met the inclusion criteria, a random sampling was carried out. Questionnaire and the informed consent forms were sent by post mail. Patients answered the corresponding 10 items in a self-administered format. A reminder letter was sent to those who did not respond after 10 days, and a reminder call was made 10 days later. In order to obtain a higher response rate, we also gave the chance of completing the survey by telephone. Items #11 and #12, which correspond to clinicians, could not be answered due to the recruitment mode, so they remained in blank, and all the analysis were performed for the 10-item TAI.

Sociodemographic (age, sex, who responded to the questionnaire, educational level and living situation) and clinical data (smoking status, forced expiratory volume in 1 second or FEV1, type or severity of COPD and asthma, exacerbations in the last year and Charlson Comorbidity Index or CCI) were collected from medical records by trained reviewers.[38,39] An instruction manual and data collection forms were used to ensure consistency among reviewers. COPD type was based on GOLD grades and severity of airflow obstruction and the type of asthma was determined by the GEMA criteria, which depends on clinical and functional parameters.[1,35] An exacerbation was defined as a worsening of respiratory symptoms that required ambulatory attendance with change in the treatment for asthma and with short-course of corticosteroids or antibiotic treatment for COPD, emergency visits, or hospitalization.

Statistical Analysis

Sociodemographic and clinical characteristics were described using frequencies and percentages for categorical variables and means and standard deviations (SD) for continuous variables.

As abovementioned, the 10-item TAI questionnaire was analyzed. Firstly, we examined the completion rate and response bias based on who completed the questionnaire (respondents vs non-respondents) according to sociodemographic variables by Fisher's exact or Chi-squared tests for categorical variables and non-parametric Wilcoxon test or *t*-test for numerical variables. Questionnaire's descriptive statistics were performed by score range and floor-ceiling effect. Either was considered to exist when the percentage of patients scoring at the lowest (10 points, floor effect) or highest (50 points, ceiling effect) level of each item or the total scale was ≥15%.[40] Patients' distribution by item responses was also evaluated.

Reliability was measured by Cronbach's alpha coefficient, which evaluates the internal consistency.[41] A value of >0.70 was established to be acceptable.[42] Besides, the item-own-scale correlation was calculated by Spearman correlation coefficient (ρ) correcting for overlap. A value of ≥0.40 was defined as satisfactory.

Construct validity was assessed by structure validity and known-groups validity.

For structure validity, confirmatory factor analysis (CFA) was used to verify that items #1 to #10 in the Basque version loaded into a unique factor, as described in the original Spanish version.[9] For that, the factor loading of each item needed to be ≥0.40. We used the robust weighted least squares estimator and defined the following criteria for goodness of fit indices as described elsewhere: root mean square error of approximation (RMSEA) <0.08, Tucker-Lewis Index (TLI) >0.90 and Comparative Fit Index (CFI) >0.90.[43] Then, the model was considered acceptable when the benchmarks were exceeded.

For known-groups validity, differences in the score were assessed by non-parametric Wilcoxon and Kruskal–Wallis tests according to patients' clinical characteristics. Clinical variables and the corresponding groups used here were the followings: type or severity of COPD [mild if FEV_1>80%, moderate if 50%<FEV_1≤80%, severe if 30%<FEV_1≤50% and very severe if FEV_1≤30%] and asthma [intermittent/mild persistent, moderate persistent or severe persistent], having at least one exacerbation in the previous year [yes/no] and CCI [1, 2 and >2]. Better TAI-measured adherence is related to exacerbation experiencing, higher disease severity and fewer comorbidities.[16,18,19] Then, we expected that patients presenting exacerbations, more severe asthma and COPD and those with CCI ≤2 would report a higher mean TAI score than their counterparts.

Statistical significance was deemed as p<0.05. All analyses were performed with SAS System software version 9.4, RStudio version 1.3 and MPlus version 6.1.[44–46]

Results

Sociodemographic and Clinical Characteristics of the Cohorts

A total of 1171 patients with asthma and 533 patients with COPD met the inclusion criteria. For cognitive debriefing, seven patients with asthma and three with COPD were recruited. For the fieldwork, a total of 617 questionnaires were sent to patients with asthma and 398 to patients with COPD, obtaining response rates of 40% and 37%, respectively, with the participation of 249 and 149 individuals. Of this sample, 215 patients with asthma (81.88%) and 122 patients with COPD (84.67%) completed the questionnaire without missing information. Completion rate depended on who responded the questionnaire (Supplementary Table 1). Descriptive characteristics of the cohorts are collected in Table 1. Mean age

Table 1 Descriptive of the Cohort

	All Patients (n=398)	Asthma (n=249)	COPD (n=149)
Sociodemographic characteristics			
Age, mean (SD)	59.43 (15.69)	53.72 (16.33)	68.96 (8.15)
Sex			
Female	194 (48.74)	157 (63.05)	37 (24.83)
Male	204 (51.26)	92 (36.95)	112 (75.17)

(*Continued*)

Table 1 (Continued).

	All Patients (n=398)	Asthma (n=249)	COPD (n=149)
Responded			
Patients by themselves	285 (75.00)	198 (84.26)	87 (60.00)
Patients with aid or proxy	95 (25.00)	37 (15.74)	58 (40.00)
Educational level			
No studies	33 (8.38)	14 (5.71)	19 (12.75)
Primary education	53 (13.45)	29 (11.84)	24 (16.11)
Secondary education, high school	191 (48.48)	110 (44.90)	81 (54.36)
University	117 (29.70)	92 (37.55)	25 (16.78)
Living situation			
Alone	45 (11.31)	28 (11.24)	17 (11.41)
With partner or others	349 (87.69)	218 (87.55)	131 (87.92)
Institutional centre, dwelling house	2 (0.50)	1 (0.40)	1 (0.67)
Other situation	2 (0.50)	2 (0.80)	0 (0.00)
Clinical characteristics			
Smoking status			
Never	164 (41.21)	148 (59.44)	16 (10.74)
Former	147 (36.93)	63 (24.90)	84 (56.38)
Current	87 (21.86)	38 (15.26)	49 (32.89)
Lung function			
FEV_1 (%), mean (SD)	81.78 (24.39)	92.81 (19.04)	64.32 (21.07)
FEV_1 (L), mean (SD)	2.85 (7.23)	2.98 (4.82)	1.81 (0.70)
Type/severity of COPD			
Mild (FEV_1>80%)	–	–	33 (23.08)
Moderate (50%<FEV_1≤80%)	–	–	71 (49.65)
Severe (30<FEV_1≤50%)	–	–	31 (21.68)
Very severe (FEV_1≤30%)	–	–	8 (5.59)
Type/severity of asthma			
Intermittent/Mild persistent	–	88 (35.34)	–
Moderate persistent	–	125 (50.20)	–
Severe persistent	–	36 (14.46)	–
Exacerbations			
No	336 (84.42)	216 (86.75)	120 (80.54)
Yes	62 (15.58)	33 (13.25)	29 (19.46)
Charlson Comorbidity Index			
1	289 (72.61)	217 (87.15)	81 (54.36)
2	73 (18.34)	21 (8.43)	40 (26.85)
>2	24 (6.03)	11 (4.42)	28 (18.79)

Notes: Unless otherwise indicated, n (%) is shown. Type or severity of COPD and asthma was determined following GOLD and GEMA recommendations, respectively.[1,35] Exacerbation was defined as a worsening of respiratory symptoms that required ambulatory attendance with change in the treatment for asthma and with short-course of corticosteroids or antibiotic treatment for COPD, emergency visits, or hospitalization.

Abbreviations: COPD, chronic obstructive pulmonary disease; FEV_1, forced expiratory volume in 1 second; GEMA, Spanish Guidelines for the management of asthma; GOLD, Global initiative for COPD; SD, standard deviation.

for asthma patients was 53.72 years (SD=16.33), 63.05% were females, 59.44% had never smoked and 50.20% presented moderate persistent asthma. Among individuals suffering from COPD, 75.17% were males with a mean age of 68.96 years (SD=8.15); 56.38% were former smokers and 49.65% were diagnosed from moderate COPD.

Descriptive Characteristics of the Questionnaire

10-item TAI mean score was 44.82 (SD=7.26) and 48.52 (SD=3.88) for asthma and COPD patients, respectively (Table 2). The percentage of participants scoring at the lowest possible level (10 points, floor effect) did not overcome the cut-off point (>15%), whereas the percentage of those scoring at the highest possible level (50 points, ceiling effect) exceeded the 15% in both asthma and COPD patients. According to the total score, adherence was stablished to be good (50 points) in the 38.14% and 67.21% of patients with asthma and COPD, respectively.

Distribution of patients by item responses is reported on Supplementary Table 2. Notably, all COPD patients chose the response-option 2 (0.80%) or 5 (99.20%) for item #10.

Reliability

Cronbach's alpha coefficients were 0.881, 0.836 and 0.880 for the cohorts of asthma, COPD, and asthma and COPD, respectively, all of them exceeding the established threshold of 0.70. Except for the item #10, item-total scale correlations also exceeded the benchmark of 0.40 (Table 3). These results demonstrate that the Basque 10-item TAI has a high internal consistency.

Table 2 Descriptive of the 10-Item TAI

	All Patients (n=337)	**Asthma (n=215)**	**COPD (n=122)**
Total score, mean (SD) Observed score range (min, max)	46.16 (6.50) 10, 50	44.82 (7.26) 10, 50	48.52 (3.88) 26, 50
% at floor, n (%) % at ceiling, n (%)	0.30 48.66	0.47 38.14	0 67.21
Level of adherence, n (%) Good (50 points) Intermediate (46–49 points) Bad (≤45 points)	 164 (48.66) 85 (25.22) 88 (26.11)	 82 (38.14) 55 (25.58) 78 (36.28)	 82 (67.21) 30 (24.59) 10 (8.20)

Notes: Theoretical score range for 10-item TAI: 10, 50 (minimum, maximum). % at floor refers to the percentage of the study population at the lowest possible scale level and % at ceiling refers to the percentage of the study population at the highest one.

Abbreviations: COPD, chronic obstructive pulmonary disease; SD, standard deviation.

Table 3 Item-Scale Correlation and Confirmatory Factor Analysis for 10-Item TAI (n=337)

	Item-Scale Correlation (ρ)	**CFA (Factor Loading)**
Item 1	0.5623	0.639
Item 2	0.5923	0.674
Item 3	0.7496	0.888
Item 4	0.7327	0.865
Item 5	0.6008	0.868
Item 6	0.4967	0.813
Item 7	0.5280	0.830
Item 8	0.5923	0.841
Item 9	0.4251	0.787
Item 10	0.2407	0.605
	RMSEA (CI 90%)	0.074 (0.051–0.097)
	CFI	0.966
	TLI	0.954
	$\chi^2(df)$	74.464 (34)

Notes: Item-scale correlation was corrected for overlap. In CFA, the correlation between the errors of items #1 and #2 was considered.

Abbreviations: CI, confidence interval; CFA, confirmatory factor analysis; CFI, comparative fit index; df, degrees of freedom; ρ, Spearman correlation coefficient; RMSEA, root mean square error of approximation; TLI, Tucker-Lewis fit index.

Table 4 Known-Groups Validity of the 10-Item TAI (n_{Asthma}=215; n_{COPD}=122)

	Asthma			COPD		
		n	Score		n	Score
Exacerbations	No Yes	185 30	44.45 (7.42) 47.10 (5.84)	No Yes	94 28	48.64 (3.21) 48.14 (5.63)
	p-value		0.0336	p-value		0.186
Type/severity of the disease	Interm./Mild P.[1] Moderate P.[2] Severe P.[3]	70 113 32	40.55 (9.06)[2,3] 46.79 (4.9)[1] 47.22 (5.81)[1]	Mild[1] Moderate[2] Severe[3] Very severe[4]	26 55 28 8	49.00 (2.12) 47.78 (4.49) 48.86 (4.51) 50.00 (0)
	p-value		<0.0001	p-value		0.046
Charlson Comorbidity Index	1 2 >2	192 14 9	44.6 (4.45) 46.4 (5.68) 46.9 (4.78)	1 2 >2	66 33 23	48.2 (4.26) 48.5 (4.27) 49.5 (1.12)
	p-value		0.3659	p-value		0.5755

Notes: 10-item TAI's mean (SD) score is shown.[1,2,3,4] Superscript letters indicate statistically significant differences in the score among patients classified according to the type of disease by non-parametric Wilcoxon test.
Abbreviations: COPD, chronic obstructive pulmonary disease; Interm, intermediate; P, persistent.

Construct Validity

Structure Validity

Fit indices in the CFA were adequate (RMSEA<0.08 and TLI and CFI>0.90) (Table 3). Factor loadings ranged from 0.605 to 0.888, satisfactorily overcoming the criteria of 0.40.

Known-Groups Validity

Total score was found to significantly increase in asthma patients who suffered from exacerbations compared to those who did not (Table 4). No changes were observed in the TAI score of patients with COPD according to exacerbation experiencing. Total score was higher in patients with more severe types of asthma (p<0.001). The results showed statistically significant differences in the TAI score according to COPD severity grades (p=0.046), but the trend was unclear. TAI score did not differ among patients with different CCI categories in any of the cohorts.

Discussion

The relevance of measuring adherence to inhaled therapy in asthma and COPD relies on its association with clinical outcomes, including lung function, exacerbations, hospital admissions and death.[4,47,48] TAI questionnaire is one of the most important PROM assessing adherence to inhaled drugs in asthma and COPD.[9,10] Here, we demonstrate that the Basque version of the TAI is a reliable and valid tool.

Mean score obtained for the Basque 10-item TAI in asthmatic patients remained within the range shown in similar Spanish studies (45.1 ± 6.6; 47.6 ±5.6) and was higher than that reported in a research from Bangladesh (36.6 ± 7.9).[13,19,49] Regarding the mean score in COPD individuals, our value was slightly higher than those described in other studies performed in Spain (47.0 ± 5.2) and Latin America (47.4 ± 4.9).[13,18] When patients with asthma and COPD were combined as a single cohort, the mean score obtained here was also in accordance with other researches from Spain (46.0 ± 6.0; 46.1 ± 5.2).[9,13]

The results showed a ceiling effect in the Basque 10-item TAI for patients with asthma and COPD, where almost half of them reported having the best therapeutic compliance. Except for the study performed by Rafi et al, similar effect was observed in most investigations in which TAI was employed, independent to the country.[13–19,49,50] In some of them, the percentage of patients having good adherence was even higher than the one we obtained.[16,49] In others, it was lower.[13–15,18,19,49,50] Then, ceiling effect is a common characteristic found in TAI that does not depends on the cultural context. It could involve a limited responsiveness to change in the upper-limit scoring, that is to say, a low capability for differentiating among highly adherent patients. Regarding the

clinical application of the TAI, this feature could be considered probably of limited clinical relevance, since the tool is focused on the identification of non-adherent patients, which are, indeed, those who would score in the lower limit. Besides, we confirm that patients suffering from COPD had better adherence to inhalers as compared to the asthmatic ones.[13–15] Importantly, social desirability bias could be a possible contributor to high adherence scores. It is usually related to patients' fear of being evaluated. In this sense, it must be underlined the self-administered postal mail recruitment mode, which is demonstrated to reduce this bias in comparison to the presence of an interviewer.[51]

Regarding the reliability, Cronbach's alpha values demonstrated that the Basque 10-item TAI is a tool with high internal consistency, as the original version is (Cronbach's alpha=0.86).[13] In other transcultural adaptations, similar or even higher reliability was obtained.[19,22–24] Lack of item-scale correlation for the item #10 is probably related to the dichotomist distribution of patients for the item's response.

Distribution of patients by item response also impeded the mathematical assessment of the questionnaire's structure separately for patients with asthma and COPD. Therefore, we needed to combine all individuals as a unique sample to assess the structure validity. Even that, CFA supported that items #1 to #10 correctly contributed into a single factor. It was then confirmed that the structure of the Basque version corresponds to the original one.[9]

Concerning known-groups validity, the results indicated that therapeutic compliance to inhaled therapy is directly associated with exacerbation experiencing in asthma, also with disease severity in asthma and COPD. These findings are in accordance with previous ones in which better adherence is linked with more severe airflow limitation and increased risk of exacerbations.[15,52] As proposed, patients with advanced asthma or COPD and heightened symptomatology consider inhaled medication to be more necessary due to medication-associated symptom-relief, which, in turn, drives a better adherence.[53] Furthermore, we could not confirm the hypotheses related to adherence and comorbidities. Importantly, the relationship between comorbidities and exacerbation with the TAI score varies among the literature in asthma and COPD.[17,20,49]

This study is not exempt from limitations. First, sending questionnaires by post mail impeded clinicians to answer items #11 and #12. In consequence, we could not characterize the non-adherence patterns in our cohort of study, nor determine their reliability and construct validity. However, we expected them to be adequate for classifying non-adherence patterns (intentional vs unintentional) because the IQOLA method was followed and experts assessed the content validity (results not shown).[32,33] Besides, 10-item TAI is a broadly used version both in validation processes and in other types of studies.[16–19,23,24,49] Anyway, while the Basque version of 10-item TAI is valid and reliable, future work should explore the full 12-item version's construct validity and reliability for richer clinical application. Coincidence of patient recruitment with the COVID-19 pandemics in Spain was the main reason to opt for postal recruitment. It could be reasonable to assume that this type of recruitment may also be the cause of the reduced response rate observed here. However, the response rate was comparable to that obtained in other Basque questionnaire validation studies.[54] Our hypothesis is that both low reading comprehension, especially in older people, and the existence of several Basque dialects are related to low response rates. Historically, Basque was a language restricted to oral communication and, therefore, development of the Standard Basque language was late and is limited, mainly, to formal registers.[55] In this sense, it must be highlighted the relevance of the cognitive interviews conducted precisely to assess the comprehensibility of the questionnaire and adapt it according to the observed needs.[34,56] Second, in order to reinforce the known-groups validity, it would be interesting to evaluate the relationship of the Basque TAI with other potential variables like control over asthma, other tools assessing generic adherence or adherence measured by electronic pharmacy medication recall systems.[9,18,24] Finally, samples were small in some groups, which could be related to the lack of statistical significance when assessing the known-groups validity. The size of both asthma and COPD cohorts met the requirement of being five to ten times the number of items for PROMs' appropriateness evaluation.[42,57] Mainly for COPD, we suggest using larger cohorts in forward researches.

Apart from adding evidence about the validity and reliability of TAI in measuring adherence to inhaled therapy, a major strengthen of our work is the cross-cultural implication of validating a PROM in a minority language like Basque. Indeed, this type of actions are crucial to meet the need for providing Basque speaker patients with an equal healthcare service.

Conclusion

Analysis of the psychometric properties of the Basque 10-item TAI demonstrates that it meets the required quality standards regarding reliability and construct validity. It is a useful questionnaire to measure adherence to inhalers in

asthma and COPD cohorts, in clinical and research settings. In future studies, clinician-rated items are recommended to include, so full psychometric properties of the 12-item TAI version can be evaluated.

Abbreviations

CCI, Charlson comorbidity index; CFA, Confirmatory factor analysis; CFI, Comparative fit index; CI, Confidence interval; COPD, Chronic obstructive pulmonary disease; FEV_1, Forced expiratory volume in one second; GEMA, Spanish guidelines for the management of asthma; GOLD, Global initiative for chronic obstructive pulmonary disease; Interm, Intermediate; IQOLA, International quality of life assessment; P, Persistent; PROM, Patient reported outcome measure; RMSEA, Root mean square error of approximation; SD, Standard deviation; TAI, Test of adherence to inhalers; TLI, Tucker-Lewis index.

Ethics Approval and Informed Consent

The study was previously approved by the ethics committee of the Barrualde-Galdakao Integrated Health Organization (Protocol number 25/20), who manages the hospital where this work was performed and who belongs to Osakidetza. It certified that the study complies with the principles of the Declaration of Helsinki, together with the General Data Protection Regulation (GDPR) 2016/679 of the European Parliament and of the Council and Organic Law 3/2018 for the management of personal data. All participants signed the informed consent form where there were stated data treatment procedures, applied principals of data governance and the right to withdraw from the study when desired.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

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