



Asthma Awareness Questionnaire: Development, Psychometric Validation, and Extent

Irene Prediletto · Benedetta Bondi · Matteo Bonini · Giovanna Elisiana Carpagnano · Manuela Latorre · Eleonora Nucera · Francesca Puggioni · Giulia Scioscia · Pierachille Santus · Giovanni Sotgiu · Francesco Blasi · Giorgio Walter Canonica · Pierluigi Paggiaro · Arianna Aruanno · Diego Bagnasco · Francesca Cefaloni · Federico Di Marco · Gabriele Fontanili · Marcello Mincarini · Giovanni Paoletti · Dejan Radovanovic · Valentina Pinelli · Francesca Ricchiuto · Pasquale Tondo · Vitaliano Nicola Quaranta · Rachele Vallara · Fulvio Braido · Ilaria Baiardini

Received: November 9, 2025 / Accepted: January 6, 2026 / Published online: February 11, 2026
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ABSTRACT

Introduction: Patient awareness extends beyond factual knowledge, encompassing emotional and cognitive engagement with the disease. As in other chronic diseases, it plays a critical role in asthma management. A comprehensive, validated tool for assessing this multifaceted construct in patients with asthma has

Fulvio Braido and Ilaria Baiardini contributed equally to the research.

I. Prediletto · G. Fontanili · R. Vallara
Dipartimento di Scienze Mediche e Chirurgiche (DIMEC), Alma Mater Studiorum Università di Bologna, Bologna, Italy

I. Prediletto
Policlinico S.Orsola-Malpighi, UO Pneumologia e Terapia Intensiva Respiratoria, IRCCS Azienda Ospedaliero-Universitaria di Bologna, Bologna, Italy

B. Bondi (✉) · D. Bagnasco · F. Di Marco · M. Mincarini · F. Ricchiuto · F. Braido
Respiratory and Allergy Clinic, IRCCS Azienda Ospedaliera Metropolitana, Genoa, Italy
e-mail: benedetta.bondi@edu.unige.it

D. Bagnasco
e-mail: diego.bagnasco@unige.it

B. Bondi · D. Bagnasco · F. Di Marco · M. Mincarini · F. Ricchiuto · F. Braido
Department of Internal Medicine (DIMI), University of Genoa, Genoa, Italy
e-mail: diego.bagnasco@unige.it

been lacking. This study aimed to develop and validate the Asthma Awareness Questionnaire (AAQ) within the framework of the Mild/Moderate Asthma Network of Italy (MANI) study, a real-world, prospective, longitudinal cohort study involving adults diagnosed with mild-to-moderate asthma according to Global Initiative for Asthma (GINA) 2020 criteria.

Methods: The questionnaire was developed through a Delphi process involving clinicians and patients. Psychometric properties (scale dimensions, internal validity, construct validity,

M. Bonini
Department of Public Health and Infectious Diseases, Sapienza Università di Roma, Rome, Italy

G. E. Carpagnano · V. N. Quaranta
Sezione di Malattie dell'Apparato Respiratorio, Dipartimento di Biomedicina Traslazionale e Neuroscienze (DiBraiN), Università degli Studi di Bari Aldo Moro, Bari, Italy

M. Latorre · V. Pinelli
UOC Pneumologia, Nuovo Ospedale Apuano (NOA), Massa, Italy

E. Nucera · A. Aruanno
Università Cattolica S. Cuore, Rome, Italy

F. Puggioni · G. W. Canonica · G. Paoletti
Department of Biomedical Sciences, Humanitas University, Pieve Emanuele, Milan, Italy

F. Puggioni · G. W. Canonica · G. Paoletti
Asthma & Allergy Unit, IRCCS Humanitas Research Hospital, Rozzano, Milan, Italy

and reliability) were explored, as well as the total and domain level of awareness.

Results: Starting from an initial list of 39 items, the Delphi process led to a provisional 22-item version. A total of 149 participants completed the AAQ at baseline and 6-month follow-up visit. Exploratory and confirmatory factor analyses supported a three-factor structure—agency, knowledge, and acceptance—with the exclusion of four items. Internal consistency (Cronbach's $\alpha=0.78$), construct validity (assessed through correlations with established patient-reported outcome measures), and test–retest reliability (ICC=0.723) were assessed. Awareness levels were suboptimal overall (mean total score $\approx 60/100$), with knowledge scores nearing the 80/100 threshold, while agency and acceptance lagged.

Conclusion: The AAQ is a psychometrically sound instrument that captures the multidimensional nature of asthma awareness. Its use may guide future interventions aimed at improving patient self-management. Further validation in broader clinical settings is warranted.

Trial registration: ClinicalTrials.gov identifier, NCT12345678.

Keywords: Asthma; Awareness; Questionnaire; Patients' education

G. Scioscia · P. Tondo
Department of Medical and Surgical Sciences,
University of Foggia, Foggia, Italy

G. Scioscia · P. Tondo
Institute of Respiratory Diseases, University
Hospital Policlinico of Foggia, Foggia, Italy

P. Santus · D. Radovanovic
Division of Respiratory Diseases, Luigi Sacco
University Hospital, Università degli Studi di
Milano, Milan, Italy

G. Sotgiu
Clinical Epidemiology and Medical Statistics Unit,
Department of Medicine, Surgery and Pharmacy,
University of Sassari, Sassari, Italy

F. Blasi
Department of Pathophysiology
and Transplantation, Università degli Studi di
Milano, Milan, Italy

Key Summary Points

Why carry out this study?

Asthma is a highly prevalent chronic respiratory disease worldwide, imposing a major socioeconomic and healthcare burden, with poor treatment adherence remaining a key unmet need despite global awareness initiatives.

Current research on asthma awareness mainly addresses patient knowledge or beliefs, but a validated instrument capturing the multidimensional nature of awareness is still lacking.

The study hypothesized that developing and validating the Asthma Awareness Questionnaire (AAQ) could provide a reliable tool to measure and enhance patient awareness, thereby supporting improved disease management and treatment adherence.

What was learned from the study?

The validation of the AAQ demonstrated robust psychometric properties, confirming its reliability and construct validity in assessing multiple dimensions of asthma awareness—including knowledge, emotional engagement, and self management attitudes—within the Mild/Moderate Asthma Network of Italy (MANI) study population.

F. Blasi
Internal Medicine Department, Respiratory Unit
and Cystic Fibrosis Center, Fondazione IRCCS Ca'
Granda Ospedale Maggiore Policlinico di Milano,
Milan, Italy

P. Paggiaro
Department of Surgery, Medicine, Molecular Biology
and Critical Care, University of Pisa, Pisa, Italy

F. Cefaloni
Department of Cardiovascular and Pulmonary
Sciences, Università Cattolica del Sacro Cuore,
Rome, Italy

I. Baiardini
Department of Health and Life Sciences, European
University of Rome, Rome, Italy

Findings highlight that greater awareness, as measured by the AAQ, correlates positively with improved adherence to therapy and better asthma control, emphasizing that patient awareness is a measurable and actionable determinant of treatment success and future intervention design.

INTRODUCTION

Asthma ranks among the most widespread chronic respiratory diseases worldwide, significantly affecting quality of life and contributing to a substantial healthcare burden [1, 2].

Disease awareness in asthma is often considered a synonym of disease knowledge [3–5]. However, awareness of an illness is not simply knowing how to detect triggers, manage the symptoms, and adhere to treatment. It involves a complex dynamic where patients assign personal significance to their knowledge while incorporating both emotional responses and cognitive understanding into their lived experience of the disease [6, 7]. While educating patients is a cornerstone for effective asthma management, true awareness is a competency that enhances self-monitoring [8] and enables “conscious intentionality,” allowing a discerning attitude regarding what to implement and what not to implement [9].

Since 2021, the Global Initiative for Asthma (GINA) has coordinated an annual World Asthma Day, an initiative that aims to increase awareness of asthma through information and educational campaigns. Despite these efforts, poor adherence to prescribed asthma therapies—especially long-term use of inhaled corticosteroids—remains a significant challenge [10]. Studies have shown that a lack of comprehensive disease understanding often correlates with reduced treatment compliance and higher rates of exacerbations [11, 12]. Enhancing patient awareness is therefore seen as a key strategy for fostering better treatment adherence and overall asthma control.

Existing literature on asthma awareness is still evolving, with research to date focusing

primarily on isolated aspects such as patient knowledge, beliefs, and treatment perceptions [13–16]. However, a standardized, validated tool for assessing the multifaceted nature of asthma awareness is still lacking. In response to this gap, our study aimed to develop and validate the novel Asthma Awareness Questionnaire (AAQ). The validation process was developed in the context of the Mild/Moderate Asthma Network of Italy (MANI) study.

METHODS

MANI Design

MANI is a cluster-based, real world, prospective, longitudinal cohort study launched by the Italian Respiratory Society and the Italian Society of Allergology, Asthma and Clinical Immunology including a population of adult patients (aged 18–80 years) with a diagnosis of mild-to-moderate asthma, defined according to Global Initiative for Asthma (GINA) 2020 criteria. This study was approved by the Ethics Committee of the Ospedale Policlinico IRCCS San Martino di Genova (N. Registro CER Liguria: 456/202068 DB id 10481 d-26/10/2020 - Delib Dir. Gen, Prot. N. 2060 11/11/2020) and performed in accordance with the Helsinki and Oviedo declarations [13, 14]. All eligible participants who freely agreed to enter the study provided written informed consent. The MANI protocol was registered at ClinicalTrials.gov under the identification number NCT04796844.

AAQ Development and Validation

A list of 39 items exploring patients’ knowledge, acceptance, and perception of asthma and awareness of treatment needs was generated by physicians and experts in health psychology, based on patients’ input and a literature search. Applying two rounds of the Delphi method [17], the 12 MANI Scientific Committee members (11 physicians, pulmonologists, and allergists who were experts in asthma treatment, and one psychologist) and 12 patients of the association *Respiriamo Insieme* identified the most relevant

items for characterizing asthma awareness, suggested additional items, and rephrased the existing ones, if appropriate. At study inclusion, MANI study patients were asked to indicate their level of agreement with the selected items (not at all/slightly/moderately/very much in agreement). The provisional version of the AAQ was completed along with other patient-reported outcome (PRO) measures: Asthma Control Test (ACT) [18], Test of Adherence to Inhalers (TAI) [19], RhinAsthma Patient Perspective (RAPP) [20], and Asthma Quality of Life Questionnaire (AQLQ) [21]. The AAQ total and domain scores were calculated by summing the non-missing items, with each item scored so that higher values indicated greater awareness. All scores were then normalized to a 0–100 scale, where a maximum overall AAQ score (100) indicated maximum awareness, and scores approaching 100 implied good levels of asthma awareness. Consistent with other PROs where scores of 80% or higher indicate achievement of the outcome [22–25], normalized scores ≥ 80 were considered to represent an optimal level of awareness. The following psychometric characteristics were evaluated: scale dimensions (exploratory and confirmatory factor analysis), internal validity, construct validity, and reliability. The AAQ total and domain scores were computed as the sum of non-missing items, after having assigned the appropriate score to each item such that higher scores reflected a higher grade of awareness. Scores were normalized to a scale ranging from 0 to 100. The levels of awareness, as well as the distribution of the AAQ total and domain scores with respect to the demographic and clinical characteristics, were evaluated at study entry.

Statistical Analysis

Exploratory factor analysis was conducted on the provisional AAQ (22 items) to identify any additional items to be removed, thereby obtaining a tool that is easier to use in clinical practice. Through this factor analysis, items 2, 5, 16, 21, and 22 were eliminated because their uniqueness value was too low (<0.20). This resulted in the 17-item version. After the exploratory factor

analysis, the following psychometric characteristics of the AAQ were evaluated:

- Internal consistency was determined by calculating Cronbach's alpha correlation coefficient on the entire test. Values of at least 0.70 are regarded as satisfactory.
- Construct validity was explored by calculating the correlation between AAQ results and ACT, AQLQ, RAPP, and TAI results.
- Test–retest reliability (i.e., stability of scores over time when no change has occurred, also called repeatability) was assessed using the interclass coefficient (ICC). A reliability coefficient of 0.70 for group comparisons and >80 for comparisons within individuals is recommended.

A two-sample *t*-test and analysis of variance (ANOVA) (or respective analogous nonparametric tests, if appropriate) were used to evaluate the associations between awareness and patient age and gender. Values of $p < 0.05$ were considered indicative of statistical significance. Analyses were performed using Jamovi[®] statistical software.

RESULTS

Starting with the initial lists, Delphi rounds led to a reduction from 39 to 22 items. Patients enrolled in the MANI completed the 22-item version. All the analyses were conducted on the questionnaires that were completed at baseline and follow-up visit by 149 patients, of whom 63.8% were female, with an average age of 55.4 ± 14.5 years. The average age of onset of the disease was approximately 37.6 ± 18.3 years. Patients who currently smoked accounted for 7.6%, with one third of patients being former smokers (33.8%). Among comorbidities, rhinitis was present in 55% of patients, with a prevalent allergic phenotype (80.2%); 13.4% of patients had chronic rhinosinusitis without nasal polyps. In terms of disease control, most patients' symptoms were controlled, with a mean ACT score of 20.7 ± 3.79 . A summary of participants' demographics and clinical characteristics is shown in Table 1. The

frequency of missing responses to each item was lower than the recommended threshold of 5% [26].

Exploratory factor analysis revealed a three-dimensional structure: items 7, 9, 12, 13, 14, 15, 16, 17, and 18 were allocated to factor 1; items 1, 2, 3, 4, 5, 19, 20, 21, and 22 were allocated to factor 2; and items 4, 6, 8, 10, and 11 were allocated to factor 3. On the basis of the findings of factor analysis and on the clinical interpretation of the preliminary results, items 2, 5, 16, 21, and 22 were removed. Based on the content of the items belonging to these factors, the first factor was denoted “agency”, the second “knowledge,” and the third “acceptance”. Subsequent analyses were then carried out on the 17-item version (Table 2).

Confirmatory factor analysis was performed for the AAQ on three factors. The overall model fitness was acceptable, where $\chi^2=809$, $p<0.001$. The model’s goodness of fit was satisfactory (root mean square error of approximation [RMSEA]=0.08, standardized root mean squared residual [SRMR]=0.05, comparative fit index [CFI]=0.9).

The internal consistency of the AAQ was good, as shown by Cronbach’s α coefficient of 0.78.

Looking at the construct validity, the correlation coefficients between the AAQ score and the ACT (Spearman rank correlation coefficient [ρ_S]=0.252, $p<0.02$), TAI ($\rho_S=0.243$, $p<0.001$), RAPP ($\rho_S=-0.640$, $p<0.001$) and AQLQ ($\rho_S=0.421$, $p<0.001$) met our expectations in terms of direction and magnitude of association. Test–retest reliability, assessed in 74 patients with no change in health status at the follow-up visit (global rating of changes scale [GRS] score=0), was satisfactory (ICC=0.723).

The levels of asthma awareness measured by the AAQ (total score and factorial scores) in patients enrolled in the study is shown in Fig. 1.

No significant correlations were found between AAQ scores and sex (ANOVA, Fisher’s test $F=0.58$, $p=0.45$) or age ($r=0.037$, $p=0.65$).

DISCUSSION

In recent years, disease awareness has become one of the foremost challenges in public health,

particularly in relation to the early detection and management of asthma—a condition significantly linked to morbidity and mortality. Over the past few decades, extensive initiatives have been implemented to enhance public understanding of the prevalence, symptoms, diagnosis, and treatment of asthma, including educational campaigns, advocacy programs, and awareness activities [27, 28]. Despite these global efforts, however, and the availability of effective treatment, current research indicates that asthma remains largely uncontrolled [29]. Since knowledge is only one aspect of awareness, a low level of overall awareness may be a primary barrier to initiating early and effective asthma management. Many patients, even when well informed about their condition, may struggle with fully understanding, accepting, and managing it. This is because awareness involves a complex process where individuals not only process accurate information but also imbue it with personal significance by integrating both cognitive and emotional elements into their experience of the disease [30]. Additional measures are essential to fully assessing all aspects of asthma awareness and developing targeted interventions. In the context of the MANI observational study, the Asthma Awareness Questionnaire (AAQ) was developed and validated following established guidelines [31]. The AAQ generates both a total score (reflecting overall awareness) and three domain-specific scores that capture knowledge, agency, and acceptance. The AAQ was found to be easily understandable by patients, showing satisfactory internal consistency, solid construct validity, and acceptable stability over time, making it a suitable tool for clinical and research applications. In the absence of a recognized “gold standard” for measuring awareness, AAQ scores were compared with patient-reported outcomes (PROs) to evaluate convergent validity. Convergent validity is typically deemed satisfactory when an instrument correlates above 0.50 with another measure of the same construct [32]. However, as previously noted [33], if the constructs under comparison only partially overlap with the one under investigation, a more flexible interpretation of correlation strength is warranted. In terms of reliability, internal consistency proved to be satisfactory.

Table 1 Baseline demographic and clinical characteristics

Variable	N = 149
<i>Demographic data</i>	
Sex	F: 63.8% M: 36.2%
Age, mean ± SD, years	55.4 ± 14.5
Ethnicity	White: 98.0% Southeast Asian: 0.7% Hispanic: 1.4%
Profession	Employed 74.6% Not employed: 3.8% Housewife: 5.4% Student: 0.8% Retired: 15.4%
BMI, mean ± SD, kg/m ²	26.2 ± 5.52
Pet owners	22.8%
Place of residence	City: 82.9% Countryside: 17.1%
Family history of asthma	22.1%
Family history of allergy	28.9%
Preterm birth	19.0%
Milky crust	13.0%
Pediatric bronchiolitis	12.8%
Smoking	Never: 58.6% Former: 33.8% Current: 7.6%
<i>Asthma features</i>	
Age of asthma onset, mean ± SD, years	37.6 ± 18.3
ACT score, mean ± SD	20.7 ± 3.79
Uncontrolled	17.0%
Partially controlled	51.0%
Controlled	32.0%
AQLQ total score, mean ± SD	5.66 ± 1.05
AQLQ symptoms	5.50 ± 1.17
AQLQ activity limitation	5.82 ± 1.05
AQLQ emotional functions	5.78 ± 1.19

Table 1 continued

Variable	N= 149
AQLQ environmental stimuli	5.50 ± 1.33
Rate of spirometry data availability at baseline	67.4%
FEV ₁ /FVC, mean ± SD	73.3 ± 8.29
FEV ₁ %, mean ± SD	90.4 ± 15.5
FVC %, mean ± SD	99.8 ± 19.2
FeNO, mean ± SD (n = 189)	32.4 ± 35.3
Blood eosinophils, mean ± SD (n = 178)	419 ± 323
Total IgE, mean ± SD (n = 151)	451 ± 840
<i>Asthma burden in the year before enrollment</i>	
Working days lost	0: 97.4% 1: 1.3% > 1: 1.3%
Spare time days lost	0: 93.2% 10: 1.4% > 10: 5.5%
ICU admissions	0.9%
Emergency room admissions	7.6%
Hospitalization for asthma	3.4%
Unscheduled visits	4.6%
One or more moderate exacerbations	0: 82.4% 1: 10.2% 2: 4.6% > 2: 2.8%
Treatment with OCS during exacerbations	0: 80.6% 1: 15.7% 2: 4.6% > 2: 2.8%
OCS days during exacerbation, mean ± SD	1.71 ± 3.97
<i>Comorbidities</i>	
Rhinitis	55.0%
Rhinitis classification	Mild intermittent: 48.3% Mild persistent: 31.0% Moderate intermittent: 1.7% Moderate persistent: 19.0%

Table 1 continued

Variable	N = 149
Allergic rhinitis	80.2%
Rhinitis duration	Perennial: 58.9% Seasonal: 41.1%
Chronic rhinosinusitis without nasal polyposis	13.4%
Atopic dermatitis	10.1%
Urticaria	8.3%
Chronic cough	8.3%
Cardiovascular diseases	16.6%
Depression	7.0%
Anxiety	8.4%
Diabetes	3.5%
Pneumonia	7.7%
Bronchiectasis	9.6%

Values are the proportion (%) of the cohort unless otherwise noted

ACT Asthma Control Test, *ACQ* Asthma Control Questionnaire, *AQLQ* Asthma Quality of Life Questionnaire, *BMI* body mass index, *FeNO* fractional exhaled nitric oxide, *FEV₁* forced expiratory volume in the first second, *FVC* forced vital capacity, *ICU* intensive care unit, *IgE* immunoglobulin E, *OCS* oral corticosteroid, *SD* standard deviation

On average, the AAQ scores (total and factorial) are unsatisfactory. In particular, only the mean scores related to knowledge of the illness approach the 80 cutoff. The total score is around 60, as are the scores for the agency and acceptance factors. These are patients who attend tertiary care centers and for whom, most likely, the information received from physicians and healthcare staff or actively sought during the disease course is adequate. Despite this, subjective dynamics come into play that make it difficult to integrate the illness into daily experience. As observed in asthma and other chronic conditions, despite being well informed, patients may encounter difficulties in translating this knowledge into action [34–36]. The way in which emotions related to the disease are experienced and regulated (acceptance) [37, 38] and the resources to cope with it [39–41] are aspects that recent literature has highlighted.

These results of our study highlight the importance of assessing all aspects of awareness. This enables us to implement appropriate

strategies not only to deepen knowledge mastery, but also to facilitate the process of disease acceptance of asthma and the sense of control over consequences, actions, thoughts, and emotions related to asthma. Tailored educational initiatives and improved communication between healthcare providers and patients may bolster understanding and coping mechanisms.

The results should be interpreted considering the limitations of the study. External validity could be limited by the nonrandom sampling approach and recruitment from specialist clinical settings. Furthermore, the acceptability of the new tool among patients and healthcare providers and the added value of using this tool in clinical practice remain unexplored. The study was conducted in a real-world clinical environment following established severity criteria for asthma classification, which are known to show variability at the individual patient level. Further research in alternative settings involving a different distribution of disease severity and symptoms would be valuable in expanding on

Table 2 Items and factors

	Item	Factor
1	I will have to continue treating asthma forever	Knowledge
2	Asthma is a chronic disease, i.e., it does not heal	Knowledge
3	Asthma is a disease that can vary in severity over time	Knowledge
4	I struggle to accept that I have asthma	Acceptance
5	I struggle with asthma symptoms	Agency
6	The idea of having to take drugs is a problem for me	Acceptance
7	Asthma worries me	Agency
8	I find it hard to say that I am asthmatic	Acceptance
9	Taking inhaled medication makes me uncomfortable	Acceptance
10	Asthma changed my life	Agency
11	I struggle to cope with asthma	Agency
12	Asthma is a difficult disease to control	Agency
13	I am worried about having to take the medication the doctor has prescribed for me	Agency
14	Asthma prevents me from doing what people my age do	Agency
15	Since being diagnosed with asthma, I no longer feel like myself	Agency
16	Inhaler medication can be discontinued when symptoms improve	Knowledge
17	Inhaled drugs, if taken continuously, lose their effectiveness	Knowledge

For each statement, the patient had to express the degree of agreement that best represented their opinion in relation to the statement. The options were as follows: strongly disagree, somewhat disagree, somewhat agree, and strongly agree

our findings. Previous studies have developed a range of surveys loosely connected to asthma awareness, though many lacked thorough validation. Some were population-based screening tools aimed at individuals unfamiliar with their risk factors for asthma, while others used online questionnaires to gauge disease perception and concerns about long-term health. Still others employed structured national surveys to highlight the need for heightened awareness of obstructive lung diseases, including asthma.

Moreover, the characteristics of this study did not allow us to evaluate the relationship between disease awareness and treatable traits [42], including psychological features such as poor symptom perception [43] and alexithymia [44], that have been shown to have an impact on asthma outcomes. These remain aspects worthy of investigation in future studies with the aim of better understanding the complexity of living with a chronic condition such as asthma.

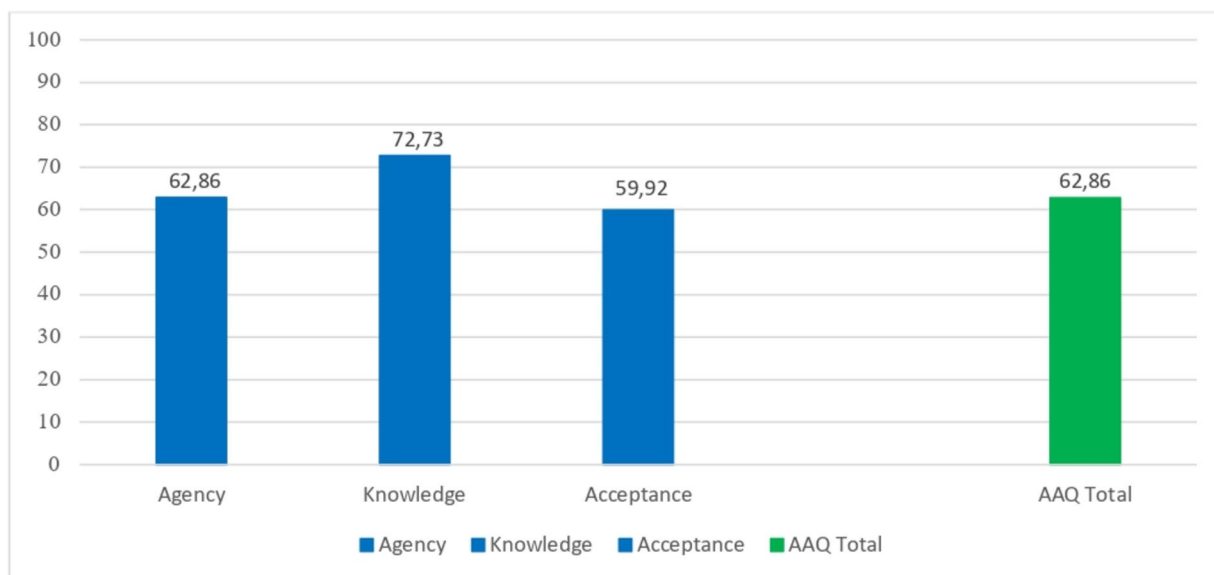


Fig. 1 Description by type of the questions, divided into the three domains that make up the questionnaire

In various clinical contexts, different awareness questionnaires have similarly indicated that enhanced patient education is crucial for improving self-management and quality of life. In contrast to these earlier efforts, the newly introduced AAQ offers a unique perspective by examining multiple dimensions of asthma awareness, including knowledge, acceptance, and agency. Assessing the level of awareness allows us to develop tailored interventions, such as educational interventions aimed at improving mastery of correct knowledge on asthma and its treatment or psychological/psychotherapeutic interventions designed to increase the individual's ability to exercise independent choice and exert influence over their own behavior and life trajectory [45], and acceptance of thoughts and feelings related to asthma.

CONCLUSION

In conclusion, this validation study confirms that the new instrument, developed and tested in a real-life setting, is valid and reliable. User-friendly for both completion and scoring. All these features make it suitable for evaluating the multifaceted nature of asthma awareness.

ACKNOWLEDGEMENTS

All the authors thank the participants of the study.

Author Contributions. Conceptualization: Ilaria Baiardini, Fulvio Braido, Methodology: Ilaria Baiardini, Fulvio Braido, Benedetta Bondi; Data Curation: Benedetta Bondi, Francesca Ricchiuto, Federico Di Marco, Marcello Mincarini, Francesca Cefaloni, Rachele Vallara, Gabriele Fontanili, Arianna Aruanno, Diego Bagnasco, Giulia Scioscia; Writing—Original Draft: Irene Prediletto, Ilaria Baiardini, Benedetta Bondi, Writing—Review & Editing: Fulvio Braido, Giovanna Elisiana Carpagnano, Matteo Bonini, Diego Bagnasco, Dejan Radovanovic, Giorgio Walter Canonica, Francesco Blasi, Pasquale Tondo, Pierluigi Paggiaro, Giovanni Paoletti, Giovanni Sotgiu, Pierachille Santus, Eleonora Nucera, Valentina Pinelli, Vitaliano Nicola Quaranta, Francesca Puggioni, Manuela Latorre; Supervision: Fulvio Braido, Ilaria Baiardini.

Funding. No funding or sponsorship was received for this study or the publication of this article. The Rapid Service Fee will be paid by the authors. The fee was funded by Fondazione per

la Salute Respiratoria della Società Italiana di Pneumologia SIP-IRS on behalf of Società Italiana di Pneumologia/Italian Respiratory Society as funder of the MANI study.

Data Availability. The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Conflict of interest. Irene Prediletto has nothing to disclose, Benedetta Bondi has nothing to disclose, Matteo Bonini has nothing to disclose, Giovanna Elisiana Carpagnano has nothing to disclose, Manuela Latorre has nothing to disclose, Eleonora Nucera has nothing to disclose, Francesca Puggioni has nothing to disclose, Giulia Scioscia has nothing to disclose, Pierachille Santus has nothing to disclose, Giovanni Sotgiu has nothing to disclose, Francesco Blasi has nothing to disclose, Giorgio Walter Canonica has nothing to disclose, Pierluigi Paggiaro has nothing to disclose, Arianna Aruanno has nothing to disclose, Diego Bagnasco has nothing to disclose, Francesca Cefaloni has nothing to disclose, Federico Di Marco has nothing to disclose, Gabriele Fontanili has nothing to disclose, Marcello Mincarini has nothing to disclose, Giovanni Paoletti has nothing to disclose, Dejan Radovanovic has nothing to disclose, Valentina Pinelli has nothing to disclose, Francesca Ricchiuto has nothing to disclose, Pasquale Tondo has nothing to disclose, Vitaliano Nicola Quaranta has nothing to disclose, Rachele Vallara has nothing to disclose, Fulvio Braido has nothing to disclose, Ilaria Baiardini has nothing to disclose.

Ethical Approval. This study was approved by the Ethics Committee of the Ospedale Policlinico IRCCS San Martino di Genova (N. Registro CER Liguria: 456/202068 DB id 10481 d-26/10/2020 -Delib Dir. Gen, Prot. N. 2060 11/11/2020) and performed in accordance with the Helsinki and Oviedo declarations [13, 14]. All eligible participants who freely agreed to

enter the study provided written informed consent. The MANI protocol was registered at ClinicalTrials.gov under the identification number NCT04796844.

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