Original article

Assessing usability of the "Adherence Starts with Knowledge 20" (ASK-20) questionnaire for Japanese adults with bronchial asthma receiving inhaled corticosteroids long term

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ABSTRACT

Background: Maintaining high treatment adherence levels is critical for effective management of chronic diseases. The Adherence Starts with Knowledge 20 (ASK-20) questionnaire is the only linguistically validated patient-reported treatment adherence tool available in Japan. We conducted additional analyses on ASK-20 data from Japanese adults with asthma.
Methods: This was a prospective, non-interventional, single-visit, multi-centre study in Japanese adults (n = 300) with asthma receiving long-term treatment with inhaled corticosteroids (ICS) or ICS/long-acting beta-agonists. We tested the reliability, validity and the relationship between different adherence conditions and ASK-20 score. At one centre, ICS adherence prescription rate was calculated retrospectively based on 2-year percentage ICS adherence data contained within medical records.
Results: The ASK-20 had good internal consistency reliability (Cronbach's alpha = 0.76; n = 290). Discriminant validity was demonstrated with significant correlations between the percentage ICS adherence rates and both the mean ASK-20 total score and mean total barrier count (TBC) (r = −0.51 and −0.58, $p < 0.001$; n = 111). The ASK-20 total score discriminated between subjects with good and poor adherence measured by patients' reported questionnaire and between those of high and low percentage ICS adherence rates. All other factors that possibly affect adherence were correlated with the mean ASK-20 total score and mean TBC in addition to the number of medicines taken every day.
Conclusions: The Japanese ASK-20 is a reliable tool for assessing possible medication adherence barriers and adherence behaviour in Japanese adults with asthma. Furthermore, our results are comparable with those obtained using the ASK-20 in the United States.

Introduction

Maintaining high levels of treatment adherence is critical for the effective management of chronic diseases.[1] Medication compliance in asthma is lower than for other chronic illnesses[2] with less than 40% of patients taking their medication as prescribed.[3] In a study by Breekveldt-Postma et al., persistence rates (defined as the number of days from start to time of first failure to continue renewal of the initial treatment) after one year were low for patients using inhaled corticosteroid (ICS) treatment (10%) and fixed combination ICS (15%),[4] which concurred with findings from an earlier pharmacy database review.[5] As such, symptoms in patients with asthma are not well controlled[6] and patients are more likely to have depressive symptoms and a lower quality of life.[7] Furthermore, non-adherence contributes to an increased number of exacerbations.[8]

Patients may not take their medication as instructed for many reasons: not fully understanding the role of their asthma treatment; not receiving clear guidelines on how to use their medication[9]; or having concerns about their treatment and associated side effects.[10]

Understanding and measuring treatment adherence is challenging, partly because of the variety of chronic conditions.[11] Variation in patients' conditions and their predisposition to hide non-adherence add to the complexity of assessment.[11] Patients who underuse their maintenance therapies tend to over-estimate the amount they take and those who overuse tend to underestimate.[12] Therefore, effective and economical tools are needed to better evaluate and improve our understanding of the barriers to treatment adherence. This, in turn, will improve communication between doctors and their patients.

Generally, treatment adherence measures are either objective, such as pill counts or the use of electronic monitoring devices, or subjective, involving self-reporting by the patient or use of physician estimates.[13,14] Adherence rates can change when different methods of assessments are used. For example, objectively measured adherence values (60.8%) were found to be significantly lower than those that had been self-reported (93.6%).[15]

Patient-reported adherence screening tools include the Morisky Medication Adherence Scale (MMAS),[16] the Medication Adherence Rating Scale (MARS)[17] and the Adherence Starts with Knowledge 20 (ASK-20) questionnaire.[11,13] Currently, only the ASK-20 is available in Japan.[18]

The ASK-20 was developed to identify and reduce the number of barriers to treatment compliance to improve adherence. It has been validated in the United States (US) and has improved our ability to identify specific treatment adherence barriers compared with other relevant patient-reporting tools.[11,13] Furthermore, the ASK-20 significantly reduces the number of adherence barriers (3.8—2.8, $p = 0.0021$) and improves control of asthma symptoms, defined as an Asthma Control Test (ACT) score >19 (50.0—64.6%; $p = 0.0285$).[19] In the US, satisfactory validity, internal consistency and reliability have also been seen with the ASK-20.[11,13] We performed a study to test the ASK-20 in Japanese adults with asthma. The linguistic validation data from this study have been published.[18] In this publication, we present outcomes from additional analyses of the original data to test the validity and reliability of the ASK-20 and investigate the impact of different adherence conditions.

Methods

Study design and population

This was a prospective, non-interventional, single-visit study conducted at 3 centres in Japan between 31 January and 20 November 2013. Approvals were given by the ethical review board at each institution: Juntendo University School of Medicine Research Ethics Committee (approval number: 962); The Fraternity Memorial Hospital Ethics Committee (113); and Toho University Omori Medical Center Ethics Committee (24-240). Written informed consent was obtained from each subject before they underwent any study measures and anonymity was preserved using methods approved by the ethical review boards. Japanese men and women aged 20 years or older were eligible if they had received ICS or ICS/long-acting beta-agonist (LABA) at a fixed dose for 2 years but had not received two or more ICS or ICS/LABA and had not visited other hospitals for bronchial asthma treatment.

Measures

At the consultation visit (baseline), subjects completed the following self-reporting questionnaires: ASK-20; ACT, to assess asthma symptoms; a questionnaire to assess the level of satisfaction with asthma treatment; and a questionnaire to assess treatment status in the previous 2 weeks. In addition, asthma severity

Table 1
Demographic characteristics of the Per Protocol population (n = 290) and the inhaled corticosteroid adherence sub-group (n = 111).

Item		Number of subjects n (%)	
		PP population[‡]	ICS sub-group
Age (years)	Overall	290	111
	Mean (standard deviation)	57.7 (16.16)	56.3 (13.92)
	Minimum—maximum	23—94	27—88
Age range, n (%)	20—34	22 (7.6)	6 (5.4)
	35—49	80 (27.6)	31 (27.9)
	50—64	80 (27.6)	40 (36.0)
	≥65	108 (37.2)	34 (30.6)
Gender, n (%)	Female	181 (62.4)	72 (64.9)
	Male	109 (37.6)	39 (35.1)
Severity of asthma, n (%)[†]	Mild	114 (39.3)	34 (30.6)
	Moderate	106 (36.6)	26 (23.4)
	Severe	70 (24.1)	51 (45.9)
Current medical history, n (%)	Respiratory	135 (46.6)	53 (47.7)
	COPD	14 (4.8)	4 (3.6)
	Perennial allergic rhinitis	65 (22.4)	21 (18.9)
	Seasonal allergic rhinitis	42 (14.5)	21 (18.9)
	Other respiratory	23 (7.9)	12 (10.8)
	Cardiovascular	82 (28.3)	29 (26.1)
	Gastrointestinal	61 (21.0)	23 (20.7)
	Renal	10 (3.4)	3 (2.7)
	Central nervous system	14 (4.8)	5 (4.5)
	Others	120 (41.4)	46 (41.4)
ACT total score, n (%)	≤19	96 (33.1)	28 (25.2)
	20—24	115 (39.7)	46 (41.4)
	25	79 (27.2)	37 (33.3)
Current use of ICS, n (%)	ICS/LABA	207 (71.4)	87 (78.4)
	Fluticasone propionate/salmeterol	131 (45.2)	61 (55.0)
	Budesonide/formoterol	76 (26.2)	26 (23.4)
	ICS alone	83 (28.6)	24 (21.6)

ACT, Asthma Control Test; COPD, chronic obstructive pulmonary disorder; ICS, inhaled corticosteroid; LABA, long-acting beta-agonist.
[†] Severity was based on the evaluation criteria of the guideline, 'Asthma Prevention and Management Guideline 2012, Japan.'[20]
[‡] Previously published data added here for comparison.[18]