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CLINICAL REPORT

Atopic Dermatitis Burden Scale for Adults: Development and Validation of a New Assessment Tool

Alain TAÏEB[1], Franck BORALEVI[1], Julien SENESCHAL[1], Stephanie MERHAND[2], Victor GEORGESCU[3], Charles TAÏEB[4] and Khaled EZZEDINE[1]

[1]Department of Dermatology, University of Bordeaux National Reference Center for Rare Skin Diseases, Hospital St-André, University Hospital Center of Bordeaux 1, Bordeaux, [2]French Association of Eczema, [3]Medical Department, Eau Thermale Avène, and [4]Public Health, Pierre Fabre, Paris, France

Atopic dermatitis (AD) occurs in approximately 2–3% of adults. The aim of this study was to develop and validate the self-administered Atopic Dermatitis Burden Scale for Adults (ABS-A). Patients were enrolled consecutively from those attending the Station Thermale Avène for a diagnosis of AD. ABS-A was developed using standard methodology, and consisted of 3 phases: exploratory, development, and validation. Internal consistency (Cronbach's α), concurrent validity (Spearman's correlation between ABS-A, SF-12 and Dermatology Life Quality Index [DLQI)]), and discriminant validity, were analysed. A total of 128 adults (68.8% females) completed the ABS-A, consisting of 18 items grouped into 4 domains. ABS-A showed good internal coherence (Cronbach's α, 0.89) and was correlated with both SF-12 components [r = –0.36, $p < 0.0001$ (Physical); r = –0.52, $p < 0.0001$ (Mental)] and DLQI (r = 0.78; $p < 0.0001$). The ABS-A score varied significantly according to AD severity. To our knowledge, ABS-A is the first specific tool for assessing AD burden in adult patients. ***Key words: adult; atopic dermatitis; individual burden; questionnaire; validation.***

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Charles Taieb, Pierre Fabre SA, 12 Avenue Hoche, FR-75008 Paris, France. E-mail: charles.taieb@pierre-fabre.com

Atopic dermatitis (AD) is a chronic, pruritic inflammatory skin disease (1, 2) that is frequently observed in children, but is also an important adult dermatological disease, affecting approximately 2–3% of adults (1, 3, 4). The global prevalence of AD has increased considerably in recent decades; it currently constitutes a major public health issue (5–7). Although potential new compounds that target pathogenesis-related AD traits are under development (8), currently available AD management options stratified according to severity (including emollients, topical steroids, systemic immunomodulators and/or phototherapy) generally aim to decrease inflammation and, consequently, may indirectly improve skin barrier function and reduce clinical signs and symptoms (e.g. pruritus) (9). Systemic treatment may be proposed for patients with moderate-to-severe AD (10–12).

It is well documented that AD is associated with a significant negative economic and quality of life (QoL) impact (13–15). Although per-patient AD costs are relatively low, a Canadian study showed that there is a large overall societal cost resulting from the prevalence of AD, with most of the cost being borne by patients and their employers, primarily due to indirect costs of absenteeism (16). Moreover, given the high prevalence of atopic manifestations (e.g. food allergies, asthma, allergic rhinitis and conjunctivitis) in AD, the total treatment costs for those who developed atopic manifestations were almost 2.5 times those associated with AD alone (17).

The notion of burden has recently been extended to individuals and their families, to assess disability (e.g. health-related QoL (HRQoL), social integration, home-life, and use of medical resources (including consultations/medications)) in the broadest sense of the term (psychological, social, economic and physical), related to various diseases including chronic venous disorders (18), hand–foot syndrome (19), infantile haemangioma (20), inherited ichthyosis (21), and osteoarthritis (22).

Despite the availability of several HRQoL tools for AD self-assessment, no specific scale currently allows the determination of AD burden, in the broadest sense, in adults. The introduction of such a tool would be beneficial for clinicians and patients in assessing AD burden in adults, and would allow evaluation of the impact of AD treatment. An AD burden scale (ABS-F) was created recently for use in families of children with AD (23). The purpose of the current study was to develop and validate the Atopic Dermatitis Burden Scale questionnaire for Adults (ABS-A).

METHODS

The self-administered ABS-A questionnaire was developed using standard methodology (24, 25) consisting of 3 phases: exploratory, development, and validation. To ensure clinical and scientific rigor, ABS-A was developed by a multidisciplinary team, comprising experts in questionnaire design/development, experts in the management and care of patients with AD (healthcare professionals, e.g. dermatologists, allergologists), patient associations, and QoL experts.

Exploratory phase

The initial exploratory step involved the creation of a verbatim report based on a review of relevant literature and qualitative face-to-face interviews between dermatologists ($n = 3$), patients with AD ($n = 12$), and an expert in questionnaire design. To determine and synthesize the main concerns, this step aimed to structure a refined objective examination and deep understanding of the difficulties experienced by patients with AD. A semi-structured questionnaire (containing precise themes and "free speech" via open-ended questions) was then administered to patients aged >18 years. Patients were enrolled consecutively from those attending the Station Thermale Avène between 1 January and 30 September 2013 for a diagnosis of AD, where they were examined by a senior dermatologist who confirmed the AD diagnosis based on United Kingdom Working Party criteria (26).

The major identified concerns of individuals with AD were consequences at work, impact on daily work and stress, daily life, everyday care, and economic constraints. Based on these concerns, the working group created the ABS-A questionnaire and individual items were converted into questions. A first assessment, simplifying the questionnaire and avoiding redundancy, was performed by the working group. ABS-A was created in a question/answer format, with response modalities determined by expert consensus (Development phase).

Development phase

During the initial development phase, the wording of possible questions/answers in the preliminary questionnaire was assessed to group similar items, remove indiscriminate questions (where >90% of subjects, regardless of gender or age, responded similarly) and limit redundancy. Item selection, to form the questions in the pilot questionnaire, was based on content and pertinence. The method of response to the questionnaire was fixed at this stage using a 6-point Likert scale ("never", "rarely", "sometimes", "often", "very often", "constantly"); to limit missing data, "Not applicable" was also included. Likert scales are often used in self-administered questionnaires (18, 19, 23) and the working group identified this method as the most relevant for ABS-A.

As a result of a subsequent pilot study to validate ABS-A (psychometric properties) and reduce the original number of questions, indiscriminate items were deleted. Based on expert panel advice, items representing similar complaints, and for which answers showed equivalent Likert scale scores, were also removed. An exploratory factor analysis (EFA) was then performed with the number of factors left free in order to highlight the underlying constructs and to categorize each item to its respective domains. To assess whether the hypothetical constructs constituting burden were interrelated, an oblique (promax) rotation was performed after an orthogonal (varimax) rotation. Items were considered for deletion if they loaded on ≥2 factors or did not load on any factors. The final questionnaire was evaluated in native French-speaking subjects during individual, cognitive debriefing interviews to determine issues with question/answer wording (ambiguity, misunderstanding, acceptability). Pilot testing was performed in France by a specialized institution (Lionbridge, Dublin, Ireland).

Dimension scores were calculated by summing individual item scores. A global score, the sum of all individual item scores, was transformed onto a 0–100 scale. A higher ABS-A score reflects a higher AD burden. ABS-A dimensions were "Daily Life", "Work and Stress", "Care & Management of Disease", and "Economic Constraints". All patients were also asked to complete a Patient-Oriented SCORing Atopic Dermatitis index (PO-SCORAD) questionnaire, to assess AD severity.

Psychometric analysis – validation

Psychometric properties were evaluated by assessing the internal consistency reliability, and the construct (concurrent and discriminant) validity of ABS-A. For internal consistency reliability, the homogeneity of items in each domain was evaluated using Cronbach's α coefficient. Coefficients of 0.6–0.69 are considered acceptable; a coefficient >0.7 generally indicates good internal reliability (27). Concurrent validity was determined by calculating the Spearman's coefficient (r) between ABS-A and 2 standard QoL questionnaires: the non-specific Short-Form-12 (SF-12) and the dermatology (not AD-specific) questionnaire, Dermatology Life Quality Index (DLQI).

Discriminant (known-group) validity was analysed according to age, gender, and AD severity and location, using the Wilcoxon and Mann-Whitney *U* test (as parameters were not distributed normally).

Data were analysed using SAS® software version 9.3 (SAS Institute Inc., Cary, USA) for Windows. A significance level of 0.05 was fixed for all tests.

Test-retest analysis

To assess the level of AD burden over a several-week period, a test–retest analysis was conducted. Subjects were retested after at least 2 weeks to allow for daily variations (28).

Table I. *Stages used for the linguistic and cross-cultural validation of Atopic Dermatitis Burden Scale-Adults (ABS-A)*

Stage	Details
1. Preparation	Evaluation of the source text from a linguistic and cultural point of view including definition of concepts
2. Forward translations	Forward translation into the required target language by 2 independent translators
3. Reconciliation	Comparison of the 2 forward translations to provide the best adaption and produce a draft version of the text
4. Back translation	Translation of the draft forward translation back into the targeted language without reference to the original language
5. Back-translation review	Comparison of the original text and the back translation to verify that the meaning of the draft translation is equivalent to source
6. Analysis and implementation of back-translation review report	Analysis of the back-translation review report to verify if there are changes required to the draft forward
7. Pilot testing	Clinical review and cognitive debriefing
8. Review of cognitive debriefing or clinical review results	Review of the results from the cognitive debriefing or clinical review to identify translation modifications necessary for improvement
9. Proofreading and finalization	Last stage, which aims to cross-cultural and validated translation of the questionnaire

Translation and cross-cultural adaptation

Following best practice (29), linguistic and cross-cultural adaptation followed a 9-step process for each language (Table I), performed by a specialized institution (Lionbridge, Ireland).

Ethical considerations

This study was approved by the Commission Nationale Informatique et Libertés (CNIL). Study participants responded anonymously to the questionnaire, which was conducted outside the framework of biomedical research.

RESULTS

Study population

Of 186 randomly selected adult patients solicited, 68.8% ($n = 128$) returned the completed questionnaire and participated in the pilot study. The study population comprised 88 females (69.0%; mean age 44 years) and 40 males (31.3%; mean age 52 years), with almost half (46.9%) of all individuals aged 35–64 years (Table II). Associated contact dermatitis, asthma, and food allergy was reported by 54.6%, 37.2%, and 51.5% of adults, respectively. AD onset occurred during infancy in 60% of patients, and after 16 years of age for the remainder. Over a third (37.6%) of all patients reported having a parent who has (or had) AD; a similar proportion (34.6%) reported that one of their children has (or had) AD. Based on the POSCORAD questionnaire, 13%, 44% and 36% of patients had mild, moderate and severe AD, respectively. One half of adults (55%) reported AD localized on the face.

Table II. *Sociodemographic and clinical characteristics of patients (n = 128) with atopic dermatitis (* p = 0.019)*

Characteristic	Male	Female
Gender, *n* (%)	40 (31.2)	88 (68.8)
Age, years, mean ± standard deviation	51.55 ± 19.64	44.2 ± 17.73*
Patient-Oriented SCORing Atopic Dermatitis index		
Mild	7 (17.5)	9 (10.2)
Moderate	18 (45.0)	38 (43.2)
Severe	12 (30.0)	34 (36.4)
Missing data	3 (7.5)	7 (7.9)
Family status, *n* (%)		
Single	4 (10.0)	13 (14.8)
Couple	21 (52.0)	42 (47.8)
Family	13 (32.0)	32 (36.4)
Missing data	2 (5.0)	1 (1.10)
Employment status, *n* (%)		
Active	19 (47.5)	46 (52.2)
Inactive	14 (35.0)	18 (20.4)
Other (e.g. student)	7 (17.1)	24 (27.7)

Exploratory phase

The initial exploratory phase involved 12 patients who discussed their complaints and disabilities related to AD, and input from 3 dermatologists and an expert in questionnaire design. The original 56 items, generated during the exploratory stage, were reduced to 19 questions.

Development phase

EFA identified a 4-group model as the most parsimonious. Of the 19 questions in the pilot questionnaire, one question ("During work I think about my eczema all the time") was deleted due to cross-loading on factors. The final version of ABS-A, which was used in the psychometric analysis, consisted of 18 items. Standardized regression coefficients were all > 0.4 on their factor (Table III).

According to standardized regression coefficients, each group of questions was assigned a dimension (each consisting of at least 3 questions): "Daily Life" (8 questions),

Table III. *Standardized regression coefficients from the final rotated factor pattern (see Methods section for details of the exploratory factor analysis)*

	Factor 1 Daily life	Factor 2 Economic constraints	Factor 3 Care and management	Factor 4 Work and stress
My eczema disrupts my daily life	**0.45565**	0.32775	0.05831	0.09605
My eczema affects how I organize my life	**0.58006**	0.24996	0.04088	0.02596
I have given up certain hobbies because of my eczema	**0.96173**	–0.07615	–0.10194	–0.07042
I choose where I will spend my vacations based on my eczema	**0.51677**	–0.19869	0.12620	0.27438
My eczema prevents me from participating in certain sports	**0.78931**	–0.07240	0.04299	–0.12585
My eczema disrupts my family life	**0.43435**	0.06059	0.30827	0.12721
My eczema affects my sleep	**0.42306**	0.26202	–0.04984	–0.01910
My eczema is the cause of tension with my significant other	0.10116	0.09332	**0.57486**	–0.21630
My family life is structured around my eczema	0.39290	–0.12271	0.19496	0.24769
Part of my budget is dedicated to treating my eczema	0.12879	**0.62139**	0.03097	0.00614
I have the impression that my eczema is costing me more and more	–0.03475	**0.69291**	0.17950	–0.01649
The foods I eat are chosen based on my eczema	0.09083	0.23434	–0.29964	**0.48060**
I dedicate a lot of time to the treatment of my eczema	0.09970	**0.44615**	0.14300	0.12937
I hesitate to buy certain medications [for my eczema] that are not reimbursed	–0.15593	**0.40569**	0.03697	0.04039
I regularly skip work to see my doctor [about my eczema]	–0.15131	0.01552	0.09265	**0.60981**
I have had to take time off from work because of my eczema	0.09287	0.02047	–0.00243	**0.64074**
I am beginning to really get tired of my daily care	–0.10408	0.16924	**0.61572**	0.07004
My daily care is wearing me out tremendously	0.10963	0.06100	**0.63229**	0.08685

Regression coefficients (in **bold**) represent the individual items included in each dimension.

"Economic Constraints" (3), "Care & Management of Disease" (3), and "Work and Stress" (4). Cognitive debriefing resulted in no major question wording changes.

Psychometric analysis – validation

All dimensions correlated well with the overall ABS-A score (highest: "Daily Life" [r = 0.87]; lowest: "Care & Management of Disease"[r = 0.62]).

Internal consistency reliability. Cronbach's α was 0.89 for the entire ABS-A questionnaire, indicating excellent internal coherence. Intra-dimensional coherences all demonstrated acceptable reliability (α > 0.61) with coherence values observed within a narrow range (α = 0.61 to 0.87).

Concurrent validity. The mean ± SD DLQI score was 9.87 ± 6.74 (range 0–30, median 8). SF-12 analysis demonstrated an altered HRQoL for the mental dimension (41.08 ± 10.7), but not for the physical dimension (50.1 ± 8.18). Individual ABS-A dimensions correlated well (inversely) with the SF-12 and, to a slightly lesser extent, with the DLQI (Table IV). As SF-12 and DLQI do not assess budgetary aspects, a lack of correlation with the "Economic Constraints" dimension of ABS-A was in line with expectations. The overall ABS-A score showed good inverse correlation with the SF-12 mental component (r = –0.52) and, to a lesser extent, with the physical dimension (r = –0.36). The overall ABS-A score showed very good correlation with the DLQI score (r = –0.78) (Table IV).

Discriminant validity. The mean ± SD ABS-A score was 31.43 ± 10.07 (median 32, range 0–53). ABS-A scores differed significantly according to gender (women experienced a heavier burden than men (29.4 ± 8.12 vs. 32.72 ± 10.17, respectively, for males and females; $p = 0.03$)), and age (patients aged < 40 years had higher scores than those aged ≥ 40 years (33.56 ± 9.44 vs. 30.06 ± 10.21; $p = 0.03$)).

Based on the PO-SCORAD, the mean ± SD ABS-A score differed significantly according to the severity of AD: mild (9.75 ± 8.93), moderate (20.61 ± 10.93), severe (33.52 ± 11.79) ($p < 0.0001$) (Table V). ABS-A scores also differed significantly according to AD location; the burden was greater in subjects reporting AD on the face compared with those not reporting AD on the face (34.08 ± 9.49 vs. 28.12 ± 9.77; $p < 0.0001$).

Test-retest analysis

The test-retest reliability of ABS-A was confirmed; an intraclass correlation (ICC) of 0.89 (95% CI, 0.80, 0.97) was obtained, demonstrating very good reproducibility. The ICC of each dimension was > 0.80.

Translation and cross-cultural adaptation

The original French version of ABS-A has been translated and has undergone linguistic and cultural adaptation in English (US), Italian and Spanish.

DISCUSSION

To our knowledge, the ABS-A is the first specific assessment tool of AD burden in adult patients. The questionnaire is available in English, French, Spanish and Italian and, if necessary, could be translated into other languages after cultural and linguistic validation.

The notion of individual burden accounts for the broadest aspects of disease-related disability, covering psychological, physical, social, and economic factors, simultaneously taking into account QoL, community integration, organization of everyday life, and medical resource consumption. This overarching burden can be evaluated directly and specifically among patients with a particular disease (18–22).

AD in adults has a negative impact on the QoL of affected individuals and their families, physiological and psychological effects, disrupts sleep patterns, behaviour and emotions, interferes with employment opportunities, and may be an independent risk factor for ischaemic stroke (14, 16, 30, 31). In a UK study of 125 adults with AD, psychological factors (particularly perceptions of stigma and associated social avoidance behaviours) and disease severity were strong QoL predictors (14). Furthermore, the large Attitude of the Adult Patient with Atopic Dermatitis (ACTIDA) study, conducted by 227 dermatologists on 1,441 analysable AD patients in Spain, showed that patients with the greatest AD flare-ups perceived their QoL to have worsened significantly compared with other AD patients. More severely affected patients also reported a greater impact on daily life, and were more concerned about their appearance, than other individuals with AD (32). Additional factors associated with the burden of AD include the financial costs

Table IV. *Correlation coefficients for the validation of the 18-question ABS-A tool vs the Short Form 12-item health survey (SF-12) and Dermatology Life Quality Index (DLQI) assessment tools*

	Daily life	Economic constraints	Care and management of disease	Work and stress	Total score
SF12-PCS	–0.33074, $p = 0.0002$	–0.26813, $p = 0.0031$	–0.23650, $p = 0.0093$	–0.30775, $p = 0.0006$	–0.36, $p < 0.0001$
SF12-MCS	–0.45800, $p < 0.0001$	–0.44767, $p < 0.0001$	0.27692, $p = 0.0022$	0.49965, $p < 0.0001$	–0.52, $p < 0.0001$
DLQI score	0.73158, $p < 0.0001$	0.58095, $p < 0.0001$	0.33430, $p = 0.0004$	0.65834, $p < 0.0001$	0.78, $p < 0.0001$

*Non-significant.

ABS-A comprises 4 domains: "Daily Life" (8 questions), "Economic Constraints" (3), "Care & Management of Disease" (3), and "Work and Stress" (4).
MCS: mental health composite score; PCS: physical health composite score.

Table V. *Distribution of mean Atopic Dermatitis Burden Scale-Adults (ABS-A) scores by the degree of atopic dermatitis severity (based on Patient-Oriented SCORing Atopic Dermatitis index (PO-SCORAD) class) (*$p < 0.0001$*)*

	PO-SCORAD class		
ABS-A score	Mild ($n=16$)	Moderate ($n=56$)	Severe ($n=46$)
Mean ± SD	9.75 ± 8.93	20.61 ± 10.93	33.52 ± 11.79
Min–Max	0–27.00	0–41.00	9.00–53.00
Median	8.50	20.00	33.50

of treatment, the purchase of special household items, time spent away from work for physician appointments, and a lack of understanding and social support from friends and family members (30, 33–35). Treatment can also be very time-consuming and stressful for patients with AD. In an analysis of the impact of AD on the total burden of illness and QoL of 298 evaluable adults and children in a large US-managed care organization, the economic impact on the healthcare system and the individual was substantial (33).

In the past decade, there has been a large increase in the availability of disease severity or QoL assessment tools for AD (36); the most frequently used disease severity tools include Severity scoring of atopic dermatitis (SCORAD and, more recently, the PO-SCORAD scale) (37), Eczema Area and Severity Index (EASI), Investigators' Global Assessment (IGA) and Six Area, Six Sign Atopic Dermatitis (SASSAD), whereas DLQI, Children's Dermatology Life Quality Index (CDLQI), Dermatitis Family Index (DFI), and Infant's Dermatology Quality of Life (IDQOL) are the most commonly used QoL measures (36). However, the majority of these scales have been developed for children with AD and there is currently no assessment scale which allows the determination of the AD burden, in the broadest sense, specifically in adults.

The current study reports the development and validation of a new tool (ABS-A) to assess the burden of AD specifically in adults. Based on this study, preliminary validation of the ABS-A has been established. Internal consistency and reliability of ABS-A was good, and the ABS-A correlated significantly with both components of the SF-12 and with the DLQI, confirming its concurrent validity. Overall, these findings with the ABS-A questionnaire concur with those reported in adults and children with AD (33), and extend and complement those reported previously in the development of the ABS-F questionnaire for assessing the burden on families of children with AD (23). Given the increasing importance that regulatory authorities have placed on PRO (38, 39), the ABS-A questionnaire aligns with the PRO concept and provides supplementary information by taking into account the burden of AD in adults in the broadest sense.

Limitations associated with the current study include the fact that the psychometric analysis was conducted in a relatively small sample of patients (predominantly females, potentially limiting data generalization) and did not test for reproducibility, measurement error, responsiveness, or interpretability. Larger confirmatory studies using the ABS-A questionnaire are warranted in order to further explore other stages of CTT, including confirmatory factorial analysis and/or rash analysis. Moreover, although ABS-A is a disease-specific assessment tool, comparison of ABS-A scores with nominal data from the general population may enhance the potential use of the tool in research and enable a more comprehensive description of the general well-being of adults with AD. Although the original ABS-A questionnaire was developed and validated in French, linguistic and cultural adaptation have subsequently made it possible for ABS-A to be available in several languages, based on best practice (29).

In dermatology there is a need for accurate tools to measure disease-specific burden measurement. The ABS-A questionnaire is a short (18-item) and easy to use tool for evaluating AD burden in adults and may allow an evaluation of the individual burden of AD before and after treatment.

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Note. A copy of the ABS-A questionnaire and the algorithm used to calculate the ABS-A score are available, on written request, from MAPI Research Trust.

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