

Translation and validation of patient-oriented eczema measure in the Greek language

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Informed consent: participation in the survey was voluntary and participants were able to withdraw their consent at any time. The collected data were anonymous and confidential.

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Abstract

Translating and validating the Greek version of the Patient Oriented Eczema Measure (POEM) was our goal. A parallel back-translation process was used to translate POEM. A total of fifty-nine adult atopic dermatitis patients were enlisted to assess validity and reliability. Through patient interviews with physicians, a questionnaire comprising demographics, POEM, and the dermatology life quality index (DLQI) was filled out. 3-7 days after the first visit, a second POEM completion was conducted. The POEM items conducted with study participants demonstrated a good level of internal consistency (Cronbach's alpha = 0.88), and no overall floor and ceiling effects were found. There was a significant correlation between the DLQI and POEM scores (Spearman rho = 0.71; p < 0.001). The POEM score between interviews showed an average intraclass correlation coefficient (95% confidence interval) of 0.89 (0.80, 0.94), indicating good to excellent test-retest reliability. Patient-reported outcome measures are becoming more and more common in Greece, so it's critical to have access to Greek translations of validated instruments that are frequently used in literature.

Introduction

Atopic dermatitis (AD) is a common chronic, often relapsing inflammatory skin disease. In a large, multinational, web-based study, the AD prevalence ranged from 2.1% to 8.1% indicating a significant incidence in the general population.¹ The burden of AD from the perspective of patients is considerable due to the impaired quality of life (QoL), psychosocial, and work functioning.^{2,3} The use of patient-reported outcome measures (PROMs) in clinical practice could provide useful insights to clinicians on how the disease impacts patients' lives and how treatment choice could benefit patients in terms of QoL or treatment satisfaction.⁴ A variety of PROMs have been introduced in AD clinical studies and healthcare in the past years addressing the need to explore the patients' experiences.⁵ Patient Oriented Eczema Measure (POEM) is a patient-oriented validated tool in the English language that assesses the atopic eczema severity which has been included in the European Medicines Agency label for dupilumab.^{6,7}

The purpose of the present study was to translate the POEM questionnaire into the Greek language and to examine the reliability and validity of the Greek version of POEM, in terms of internal consistency, repeatability, and concurrent validity.

Materials and Methods

Tool translation

The POEM translation from the original English version into Greek was carried out according to the parallel back-translation procedure and in accordance with the translating guidelines of the owner of the tool (Nottingham University); two bilingual individuals, who were familiar with AD, independently translated the original tool into Greek, while a local doctor and a patient with eczema were asked about the words they use to describe terms within POEM which may be difficult to translate (e.g., ‘oozing clear fluid’ and ‘flaking off’).

Thereafter, a Greek translation was developed and another bilingual person who was not familiar with the original tool re-translated the Greek version into English. The original English version and the re-translated one were compared in a conceptual manner. The Greek translation of POEM for adults is currently available on the Nottingham University website.⁸

Study design

To evaluate the reliability and validity of the Greek version of POEM, patients were recruited from a secondary care setting of the Department of Dermatology located at Andreas Syggros Hospital of Cutaneous and Venereal Diseases in Athens, Greece between April 16, 2021, and December 12, 2021. All patients were adults, they satisfied the diagnostic criteria for atopic eczema of Hanifin and Rajka and were under an ongoing conventional systemic treatment.

The present study is in accordance with the Declaration of Helsinki, while the study approval was given by the hospital’s Ethics Committee. Participation in the survey was voluntary and participants were able to withdraw their consent at any time. The collected data were anonymous and confidential.

Data collection and sample size estimation

A structured questionnaire was developed including demographic characteristics (gender, age, race), the Greek translation of the POEM questionnaire and the Greek version of the Dermatology Life Quality Index (DLQI); the DLQI score ranges from 0 to 30 and a higher score indicates more impaired QoL.⁹ AD severity was defined with the use of the DLQI and POEM bandings proposed by Silverberg *et al.*¹⁰ Those who consented to participate in the study answered the study questionnaire during their visit in the secondary care setting and scheduled a telephone interview 3-7 days after the initial visit when they completed the POEM questionnaire for a second time. Participants with incomplete POEM data were excluded from the analysis.

Considering the repeatability of the tool and assuming a confidence level of 95%, a power of 85%, a minimum acceptable reliability of 70%, and an expected reliability of 86%, a sample size of 51 patients was estimated as adequate.

Statistical analysis

The baseline characteristics of the participants are presented with median (1st-3rd quartile) for continuous variables and with absolute (n) and relative (%) frequencies for categorical variables. Descriptives for questionnaires are reported with mean and standard deviation (SD).

The internal consistency of the POEM questionnaire was determined using Cronbach’s alpha and Pearson correlation between the individual tool items. Test-retest reliability of POEM was analyzed using the Bland and Altman method and the intraclass correlation coefficient (ICC) [presented with mean and 95%

confidence interval (CI)] in participants with complete POEM data in both study interviews, while for the POEM severity stages were addressed with the weighted Cohen’s kappa coefficient due to the ordinal nature of this variable (Figure 1). Spearman rank correlation was performed to compare POEM, and DLQI scores in order to assess the concurrent validity of the Greek POEM translation. The agreement of AD severity based on DLQI and POEM questionnaires was assessed with the use of the weighted kappa coefficient, as well. Floor and ceiling effects of the total POEM scores were considered present if 15% of responses fell in the lowest or highest scores. All analyses were performed at a 5% level of statistical significance using the statistical program STATA 17.0.

Results

In total, 59 patients were recruited in the study; from those 58 and 52 had completed adequately the POEM questionnaire in 1st and 2nd interviews, respectively. The median (1st-3rd quartile) age of participants was 39.9 (23.8-46.0) years and the majority were female (63.8%). All participants with a recorded race were Caucasian (n=54).

During the 1st interview, the mean (SD) POEM and DLQI score was 12.7 (7.6) and 10.3 (7.5), respectively. During the 2nd interview, the mean (SD) POEM was 11.7 (7.6). With regards to the POEM items, the mean (SD) scores for itchy, sleep, bleeding, weeping, crack-ling, flaking, and dry/rough items, were 2.71 (1.40), 1.41 (1.43), 1.38 (1.31), 1.09 (1.32), 1.76 (1.51), 1.79 (1.58) and 2.57 (1.41) respectively, while for the 2nd visit, the corresponding mean (SD) scores were 2.46 (1.36), 1.06 (1.33), 1.12 (1.32), 0.85 (1.14), 1.81 (1.44), 1.79 (1.64), and 2.60 (1.52).

Test-retest reliability

The mean (SD) of POEM score differences between the two interviews was 1.27 (2.46). The average ICC (95% CI) of POEM score between interviews was estimated at 0.89 (0.80, 0.94) indicating good to excellent reliability. The weighted kappa coefficient of POEM severity stages was estimated at 0.63 indicating a moderate level of agreement (88.9%).

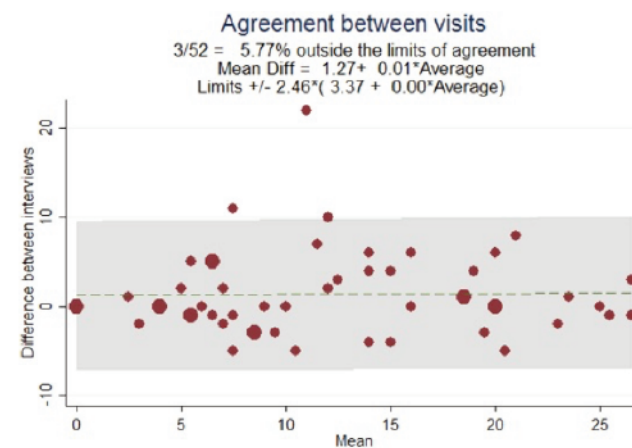


Figure 1. Bland and Altman plot for patient-oriented eczema measure.

Internal consistency

All POEM items (*i.e.*, itchy, sleep, bleeding, weeping or crackling, cracking, flaking) showed good internal consistency among study participants in both assessments [1st interview (n=85): Cronbach's alpha =0.88; 2nd interview (n=52): Cronbach's alpha =0.89], with weak-to-moderate interitem correlations (Cronbach's alpha range for 1st visit: 0.29-0.77; for 2nd visit: 0.35-0.71) (Table 1).

Concurrent validity

The POEM and DLQI scores were significantly correlated (Spearman rho =0.71; p<0.001). Moreover, based on the AD severity levels as defined with 3 different bandings for DLQI and one for the POEM questionnaire, the weighted kappa coefficient ranged from 0.51-0.55 (Table 2).

Floor and ceiling effects

The proportions of patients with the lowest and highest values for POEM score as collected in the 1st interview (5.17% for score equal to 0 and 1.72% for score equal to 28) and in the 2nd interview (5.77% for score equal to 0 and 1.92% for score equal to 27), were below 15% indicating the absence of floor and ceiling effects for the overall POEM score. However, multiple POEM items had either floor or ceiling effects during both visits. More specifically, during the 1st interview, floor effects (score equal to 0) were observed for sleep (36.2%), bleeding (29.3%), weeping (46.6%), cracking (25.9%) and flaking (27.6%) items, while ceiling effects (score equal to 4) were observed for itchy (46.6%), cracking (20.7%), flaking (25.9%) and dry/rough (39.7%) items. During the 2nd interview, floor effects were observed for sleep (48.1%), bleeding (42.3%), weeping (51.9%), cracking (17.3%), flaking (28.9%)

Table 1. Interitem correlations of patient-oriented eczema measure items (Pearson's rho coefficient).

1 st interview, n=58	Itchy	Sleep	Bleeding	Weeping	Crackling	Flaking
Itchy	1.00					
Sleep	0.67	1.00				
Bleeding	0.49	0.46	1.00			
Weeping	0.38	0.29	0.34	1.00		
Crackling	0.62	0.57	0.62	0.46	1.00	
Flaking	0.53	0.51	0.39	0.50	0.50	1.00
Dry or rough	0.77	0.66	0.42	0.41	0.60	0.61
2 nd interview, n=52						
Itchy	1.00					
Sleep	0.61	1.00				
Bleeding	0.51	0.65	1.00			
Weeping	0.50	0.35	0.52	1.00		
Crackling	0.67	0.58	0.71	0.47	1.00	
Flaking	0.48	0.38	0.53	0.43	0.71	1.00
Dry or rough	0.69	0.54	0.39	0.41	0.53	0.47

Table 2. Atopic dermatitis severity based on patient-oriented eczema measure and dermatology life quality index questionnaires.

	1 st interview N=58	2 nd interview N=52	Weighted Kappa coefficient (% of agreement)*
AD severity based on DLQI, n (%)	N=57		
Banding 1			
Mild (score: 0-5)	19 (33.3%)	n/a	0.51 (78.1%)
Moderate (score: 6-10)	14 (24.6%)		
Severe (score: 11-30)	24 (42.1%)		
Banding 2			
Mild (score: 0-4)	16 (28.1%)	n/a	0.55 (82.5%)
Moderate (score: 5-14)	27 (47.4%)		
Severe (score: 15-30)	14 (24.6%)		
Banding 3			
Mild (score: 0-4)	16 (28.1%)	n/a	0.51 (83.3%)
Moderate (score: 5-22)	36 (63.2%)		
Severe (score: 23-30)	5 (8.8%)		
AD severity based on POEM, n (%)			
Mild (score: 0-7)	18 (31.0%)	18 (34.6%)	
Moderate (score: 8-19)	28 (48.3%)	24 (46.2%)	
Severe (score: 20-28)	12 (20.7%)	10 (19.2%)	

AD, atopic dermatitis; DLQI, dermatology life quality index; POEM, patient-oriented eczema measure; n/a, not assessed. *Relative to POEM AD severity levels at 1st interview.

and dry/rough (17.3%) items and ceiling effects were observed for itchy (36.5%), cracking (21.2%), flaking (30.8%) and dry/rough (42.3%) items (data not presented).

Discussion

The current study provided a Greek translation for the POEM questionnaire and explored the validity of this tool in adults with AD located in Greece. The Greek translation has already been accepted by the creators of the POEM questionnaire.⁸

It was found that the Greek translation had good internal consistency, acceptable concurrent validity, and good to excellent test-retest reliability. The POEM and DLQI scores were significantly correlated in our study, and no overall floor and ceiling effects were detected, results which are in accordance with the findings of Silverberg *et al.*¹¹ In another publication of Silverberg *et al.*, POEM had significant floor effects which could be explained due to a large proportion of United States adults with AD having only very mild disease.¹²

The good internal consistency of the POEM questionnaire found in our study was comparable with the findings of other researchers.^{12,13} Considering test-retest repeatability, the mean (SD) of POEM score differences between the two interviews was 1.27 (2.46), which was higher compared to the findings of Charman *et al.*⁶

This study is subjected to several limitations. The sample came from a single dermatologic clinic of an Athens-based hospital and even though this hospital is the largest Dermatological Hospital in Greece, the generalization of the results in the overall Greek AD adult population is questionable. An additional limitation was that the AD severity was collected only with PROMs and a clinical assessment had not been provided. Among the strengths of the study was the priory sample size estimation and the selection of AD patients with a stable disease, which added value to the strength of the quality of the results.

Conclusions

As the use of PROMs in the Greek setting is increasing, it is important to have access in Greek translated and validated tools that are commonly used in the literature as the POEM questionnaire in the AD population.

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