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

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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.

Availability of data and material: data and materials are available by the authors.

#### Abstract

Our purpose was to translate and validate the Patient Oriented Eczema Measure (POEM) in Greek. POEM translation was carried out with parallel back-translation procedure. To examine reliability and validity, 59 AD adult patients were recruited. A questionnaire including demographics, POEM, and Dermatology Life Quality Index (DLQI) was completed through physicians' interview with patients. A second POEM completion took place 3-7 days after the initial visit. POEM items showed good internal consistency among study participants [Cronbach's alpha = 0.88] and no overall floor and ceiling effects were detected. The POEM and DLQI scores were significantly correlated (Spearman rho = 0.71; p<0.001). The average ICC (95% CI) of POEM score between interviews was 0.89 (0.80, 0.94) indicating good to excellent test-retest reliability. As the use of patient reported outcome measures in Greece is increasing, it is important to have access in Greek translated - validated tools that are commonly 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, psychosocial and work functioning.(2,3)

The use of patient-reported outcome measures (PROMs) in the clinical practice could provide useful insights to clinicians on how the disease impacts patients life and how treatment choice could benefit patients in terms of quality of life 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 assess the atopic eczema severity which has been included in the European Medicines Agency (EMA) label for dupilumab.(6,7)

The purpose of the present study was to translate the POEM questionnaire in 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 in 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. The participation in the survey was voluntary and participants were able to withdraw their consent at any time. 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 POEM questionnaire and the Greek version of Dermatology Life Quality Index (DLQI); the DLQI score ranges from 0 to 30 and 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. (2018).(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 ( $1^{st} - 3^{rd}$  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 POEM questionnaire was determined using the Cronbach's alpha and Pearson correlation between the individual tool items. Test-retest reliability of POEM was analysed 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 was addressed with the weighted Cohen's kappa coefficient due to the ordinal nature of this variable. 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 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 in 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  $1^{st}$  and  $2^{nd}$  interview, respectively. The median ( $1^{st} - 3^{rd}$  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 re-gards 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 Bland and Altman plot is shown in **Errore. L'origine riferimento non è stata trovata.** 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%).

### Internal consistency

All POEM items (i.e., itchy, sleep, bleeding, weeping or crackling, crackling, flaking) showed good internal consistency among study participants in both assessments [1st in-terview (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 POEM questionnaire, the weighted kappa coefficient ranged from 0.51 - 0.55 (Errore. L'origine riferimento non è stata trovata.).

# 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 of 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%) 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**

Insert the text of the discussion here. The current study provided a Greek translation for 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 POEM questionnaire.(8)

It was found that the Greek translation had good internal consistency, an acceptable concurrent validity and a 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 U.S. adults with AD having only very mild disease. (12)

The good internal consistency of 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 were 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 a priory sample size estimation and the selection of AD patients with a stable disease, which added value in 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.

#### References

- 1. Barbarot S, Auziere S, Gadkari A, Girolomoni G, Puig L, Simpson EL, et al. Epidemiology of atopic dermatitis in adults: Results from an international survey. Allergy Eur J Allergy Clin Immunol. 2018;73(6):1284–93.
- 2. Girolomoni G, Luger T, Nosbaum A, Gruben D, Romero W, Llamado LJ, et al. The Economic and Psychosocial Comorbidity Burden Among Adults with Moderate-to-Severe Atopic Dermatitis in Europe: Analysis of a Cross-Sectional Survey. Dermatol Ther (Heidelb) [Internet]. 2021;11(1):117–30. Available from: https://doi.org/10.1007/s13555-020-00459-8
- 3. Whiteley J, Emir B, Seitzman R, Makinson G. The burden of atopic dermatitis in US adults: results from the 2013 National Health and Wellness Survey. Curr Med Res Opin. 2016;32(10):1645–51.
- 4. Field J, Holmes MM, Newell D. PROMs data: can it be used to make decisions for individual patients? A narrative review. Patient Relat Outcome Meas [Internet]. 2019 Jul;Volume 10:233–41. Available from: https://www.dovepress.com/proms-data-can-it-be-used-to-make-decisions-for-individual-patients-a--peer-reviewed-article-PROM

- 5. Barrett A, Hahn-Pedersen J, Kragh N, Evans E, Gnanasakthy A. Patient-Reported Outcome Measures in Atopic Dermatitis and Chronic Hand Eczema in Adults. Patient Patient-Centered Outcomes Res [Internet]. 2019 Oct 4;12(5):445–59. Available from: http://link.springer.com/10.1007/s40271-019-00373-y
- 6. Charman CR, Venn AJ, Williams HC. The patient-oriented eczema measure: development and initial validation of a new tool for measuring atopic eczema severity from the patients' perspective. Arch Dermatol. 2004 Dec;140(12):1513–9.
- 7. Charman CR, Venn AJ, Ravenscroft JC, Williams HC. Translating patient-oriented eczema measure (POEM) scores into clinical practice by suggesting severity strata derived using anchor-based methods. Br J Dermatol. 2013;169(6):1326–32.
- 8. Gregoriou S. Greek POEM translation [Internet]. Centre of Evidence Based Dermatology University of Nottingham. 2022. Available from: https://www.nottingham.ac.uk/research/groups/cebd/resources/poem.aspx
- 9. Finlay AY, Khan GK. Dermatology Life Quality Index (DLQI)-a simple practical measure for routine clinical use. Clin Exp Dermatol [Internet]. 1994 May;19(3):210–6. Available from: http://doi.wiley.com/10.1111/j.1365-2230.1994.tb01167.x
- 10. Silverberg JI, Gelfand JM, Margolis DJ, Fonacier L, Boguniewicz M, Schwartz LB, et al. Severity strata for POEM, PO-SCORAD, and DLQI in US adults with atopic dermatitis. Ann Allergy, Asthma Immunol [Internet]. 2018 Oct;121(4):464-468.e3. Available from: https://linkinghub.elsevier.com/retrieve/pii/S1081120618305362
- 11. Silverberg JI, Lei D, Yousaf M, Janmohamed SR, Vakharia PP, Chopra R, et al. Comparison of Patient-Oriented Eczema Measure and Patient-Oriented Scoring Atopic Dermatitis vs Eczema Area and Severity Index and other measures of atopic dermatitis. Ann Allergy, Asthma Immunol [Internet]. 2020 Jul;125(1):78–83. Available from: https://linkinghub.elsevier.com/retrieve/pii/S1081120620301502
- 12. Silverberg JI, Margolis DJ, Boguniewicz M, Fonacier L, Grayson MH, Ong PY, et al. Validation of five patient-reported outcomes for atopic dermatitis severity in adults. Br J Dermatol [Internet]. 2019 Jul 24;bjd.18002. Available from: https://onlinelibrary.wiley.com/doi/abs/10.1111/bjd.18002
- 13. Charman CR, Venn AJ, Williams HC. The Patient-Oriented Eczema Measure. Arch Dermatol. 2004;140(12):1513–20.

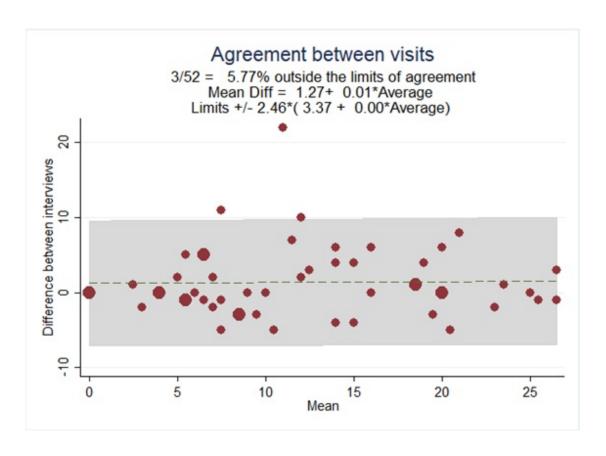


Figure 1. Bland and Altman plot for patient-oriented eczema measure.

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

1 <sup>st</sup> 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 <sup>nd</sup> 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.

			Weighted Kappa	
	1 <sup>st</sup> interview	2 <sup>nd</sup> interview	coefficient	
	N=58	N=52	(% of agreement)	
			*	
AD severity based on DLQI, n (%)	N=57			
Banding 1				
Mild (score: 0 – 5)	19 (33.3%)			
Moderate (score: 6 – 10)	14 (24.6%)	n/a	0.51 (78.1%)	
Severe (score: 11 – 30)	24 (42.1%)	-		
Banding 2				
Mild (score: 0 – 4)	16 (28.1%)			
Moderate (score: 5 – 14)	27 (47.4%)	n/a	0.55 (82.5%)	
Severe (score: 15 – 30)	14 (24.6%)	1		
Banding 3				
Mild (score: 0 – 4)	16 (28.1%)			
Moderate (score: 5 – 22)	36 (63.2%)	n/a	0.51 (83.3%)	
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 (20.75)	10 (19.2%)		

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