



Tools to Measure Hand Eczema Severity

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Disclosure of Relevant Relationships with Industry

Advisory Board: Arcutis, Arena, Asana, Eli Lilly, Galderma, Incyte, LEO Pharma, Pfizer, RAPT Therapeutics

Investigator: AbbVie, Arcutis, Asana, Bellus, Boehringer-Ingelheim, Cara, Dermavant, Eli Lilly, Incyte, Novan, Pfizer, RAPT Therapeutics, Sanofi Genzyme, Target RWE

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Hand Eczema Severity



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Tools used to measure Hand Eczema

- Systematic literature search (Pubmed + Cochrane)
- Articles on « Methods quantifying hand eczema »
- Performed in 2009
- 69 articles identified with 45 different methods
- Only a small number reported inter and intra-observer reliability

Weistenhofer et al Br J Dermatol 162: 239; 2010



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Hand Eczema Lesion severity Evaluation

- Hands are easier to examine than whole body
 - No hair
 - No clothing
 - No folds
 - Less lighting effect
- Morphology can be different on palms and back of hands
- Higher variability in lesion type as compared with AD



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Main Tools to measure severity of Hand Eczema

- PGA/IGA
- HECSI
- mTLSS
- HEES
- Quality of life
 - QOLHEQ
 - DLQI
 - BoHEM
 - Pain and Pruritus NRS



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Physician (Investigator) Global Assessment (PGA/IGA)



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Physician Global Assessment

Scale used for allitretinoin in phase 3

PGA severity	Features	Intensity	Area involved*
Severe	E, S, H/L V, O, F, P/P	At least one moderate or severe At least one severe	> 30% of affected hand surface
Moderate	E, S, H/L V, O, F, P/P	At least one mild or moderate At least one moderate	10%-30% of affected hand surface
Mild	E, S, H/L V, O, F, P/P	At least one mild At least one mild	Less than 10% of affected hand surface
Almost clear	E, S, H/L V, O, F, P/P	At least one mild Absent	Less than 10% of affected hand surface
Clear	E, S, H/L V, O, F, P/P	Absent Absent	Not detectable

E=Erythema, S=Scaling, H/L=Hyperkeratosis/Lichenification, V=Vesiculation, O=Oedema, F=Fissures, P/P=Pruritus/Pain



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PGA Photonumeric scale



Coenraads et al Br J Dermatol 152: 296; 2005



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Hand Eczema Severity Index (HECSI) Intra-observer variability

- 15 patients with CHE
- 12 physicians experienced in hand eczema evaluations
- Physicians received training on how to use the scale
- Objectives: evaluate intra and inter-observer variability
- Evaluations
 - Hands of all patients evaluated by MD
 - Order of the 15 patients changed
 - Hands of all patients evaluated by MD 30 minutes later

Held et al Br J Dermatol 152: 302; 2005



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HECSI Inter-observer Intra-class correlation coefficient

	ICC, absolute agreement (lower 95% CI)	ICC, consistency (lower 95% CI)
Total HECSI score 1	0.79 (0.65)	0.81 (0.68)
Total HECSI score 2	0.84 (0.72)	0.89 (0.81)

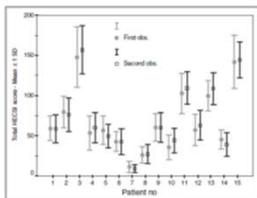
0.4-0.75 fair to good agreement
> 0.75 excellent agreement

Held et al Br J Dermatol 152: 302; 2005



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Hand Eczema Severity Index (HECSI) Intra-observer variability



ICC Intra-observer 0.9

Held et al Br J Dermatol 152: 302; 2005



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Modified Total Lesion Symptom Score (mTLSS)



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mTLSS

- Modification of a previously published scale
- Used in phase 3 trials with alitretinoin
- Performed on most affected side of most affected hand
- Equivalent of a « Target lesion » type of assessment (not all lesions evaluated)

Ruzicka et al Br J Dermatol 158: 808; 2008



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mTLSS

Parameter	Description of Severity ^a
Erythema	0 = Absent
	1 = Faint erythema
	2 = Prominent redness
3 = Deep serum red color	
Scaling	0 = Absent
	1 = Slight flaking over limited areas, mostly fine scales
	2 = Flaking over widespread area(s), coarse scales
	3 = Desquamation covering over 30% of the hand, with coarse thick scales
Lichenification/ hyperkeratosis	0 = Absent
	1 = Mild thickening with exaggerated skin lines over limited areas
	2 = Papular thickening over widespread area(s)
3 = Prominent thickening over widespread area(s) with exaggeration of normal skin markings	
Vesicles	0 = Absent
	1 = Scattered vesicles affecting up to 10% of hand, without oozing
	2 = Scattered or clustered vesicles affecting up to 30% of hand, without visible oozing or crusting
3 = High density of vesicles extending over large area(s), or with oozing or crusting	
Oedema	0 = Absent
	1 = Dermal swelling over less than 10% of hands
	2 = Diffuse dermal swelling over more than 10% of hand
3 = Dermal swelling with skin induration over widespread area(s)	
Fissures	0 = Absent
	1 = Cracked skin affecting a small area of the hand
	2 = Cracked skin affecting multiple areas of the hand and causing pain
	3 = One or more deep fissures and causing bleeding or severe pain
Pruritus/pain	0 = Absent
	1 = Occasional, slight discomfort a few times per day
	2 = Intermittent, causing discomfort frequently during the day
3 = Persistent or interfering with sleep	

^a 0 = absent, 1 = mild, 2 = moderate, 3 = severe

Ruzicka et al Br J Dermatol 158: 808; 2008



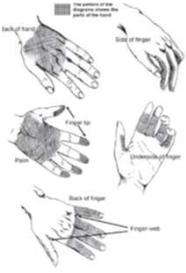
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Hand Eczema Extent Score



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HEES



Carlsson et al Acta Dermatol Venereol 97:193; 2017



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HEES

Right hand					
	Entire area = more than 2/3			Part of the area = less than 2/3	
Back of hand	<input type="checkbox"/>			<input type="checkbox"/>	
Palm	<input type="checkbox"/>			<input type="checkbox"/>	
	Back of finger	Side of finger	Underside of finger	Finger lip	Nail changes
Thumb	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Index finger	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Middle finger	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ring finger	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Little finger	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Finger-web between...	Thumb and index finger			<input type="checkbox"/>	
	Index finger and middle finger			<input type="checkbox"/>	
	Middle finger and ring finger			<input type="checkbox"/>	
	Ring finger and little finger			<input type="checkbox"/>	

Carlsson et al Acta Dermatol Venereol 97:193; 2017



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HEES intra/inter-observer reliability

- 18 patients (2 sessions)
- 6 dermatologists
- HEES performed in AM and PM on the same day
- Patients also performed self-assessment (HEES)

Carlsson et al Acta Dermatol Venereol 97:193; 2017

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HEES intra/inter-observer reliability

- Inter-observer ICC 0.82
- Intra-observer ICC dermatologists 0.99-0.94
- Intra-observer ICC patients 0.90 – 0.97

Carlsson et al Acta Dermatol Venereol 97:193; 2017

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Quality Of Life Hand Eczema Questionnaire (QOLHEQ)

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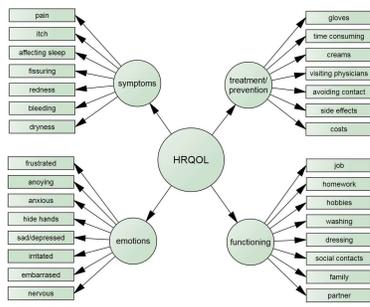
QOLHEQ

- Developed in Germany, validated in other languages
- Specific for hand eczema
- Assesses hand-specific quality of life over past 7 days
- Consists of 30 items
- 5-point NRS

http://qolheq.dermis.net/content/home/index_eng.html



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http://qolheq.dermis.net/content/home/index_eng.html



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Validation of QOLHEQ



Correlation with DLQI, PGA (low: 0.3), Skindex-17 And EQ-5D

ICC = 0.9

More sensitive than generic QoL Quest

Ofenloch et al Br J Dermatol 171: 304; 2014



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Dermatology Quality of Life Index (DLQI)



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DLQI

- Questionnaire to measure Quality of Life in patients with dermatological diseases
- 10 questions on various topics related to QoL
- Patients need to answer on a scale of 0 to 3 based on the past week
- Most widely used QoL in Dermatology
- Translated into more than 115 languages

Finlay et al. Br J Dermatol 129:27; 1993



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DLQI

- Questions with no correlation with patient-rated severity score
 - Question 4 : clothes worn
 - Question 6 : impairment of sporting activities
 - Question 10: problems associated with treatment of skin
- Questions with highest burden of disease
 - Question 1: pain/pruritus
 - Question 3: shopping

Van Coevorden et al Br J Dermatol155: 217; 2006



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BoHEM

- Burden of Hand Eczema
- 15 patients shared their complaints, perception and experience in relation with CHE
- 15 questions related to daily lives, perceived appearance to other and relationship
- Answers are from 0 (never or not applicated) to 5 (constantly)
- Total score from 0 to 75
- Validation performed for French and English versions

Macari et al J Am Acad Dermatol 80: 1784; 2019



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BoHEM

Table 1. Loading of questions on the factors after rotation

Item	Factor 1	Factor 2	Factor 3
I have difficulty performing everyday activities.	0.65	0.27	0.05
My professional activities are impacted.	0.62	0.38	0.05
I have difficulty grooming (styling hair, washing, shaving).	0.69	0.17	0.21
I have had problems at work due to my chronic hand eczema.	0.65	0.25	0.08
Daily care for my chronic hand eczema is immensely tiring.	0.76	0.04	0.27
It seems to me that my chronic hand eczema is costing me more and more.	0.70	0.17	0.22
My chronic hand eczema affects my quality of sleep negatively.	0.69	0.23	0.21
I believe that my life would have been different without chronic hand eczema.	0.61	0.25	0.28
When I show my hands, the looks from other people embarrass me.	0.32	0.70	0.22
I hesitate to shake hands when meeting someone.	0.35	0.56	0.15
I tend to keep my hands in my pockets.	0.15	0.60	0.15
I don't know where to put my hands anymore when at work.	0.17	0.82	0.17
Interacting with others is difficult.	0.41	0.50	0.46
I have a troubled emotional life.	0.28	0.26	0.84
The appearance of my hands (redness, dryness) affects my sex life.	0.18	0.17	0.80

Macari et al J Am Acad Dermatol 80: 1784; 2019



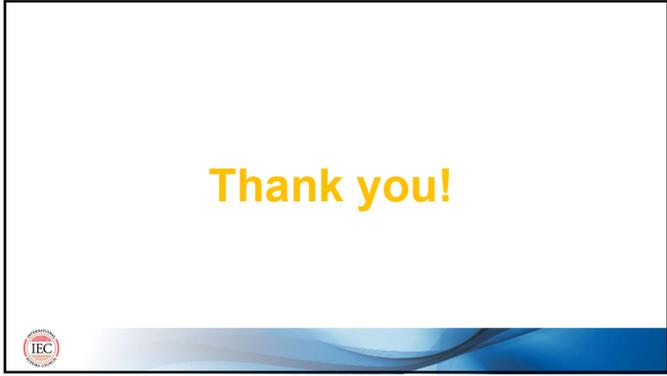
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Conclusions

- PGA/IGA
 - Need for a validated PGA/IGA tool for Chronic Hand Dermatitis
- Lesion severity
 - HECSI
 - mTLSS
 - HEES
- Quality of life
 - QOLHEQ
 - DLQI
 - BoHEM



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