[SAT0583] A SYSTEMATIC REVIEW OF SYSTEMIC SCLEROSIS INSTRUMENTS FOR THE EULAR OUTCOME MEASURES LIBRARY: AN EVOLUTIONARY DATABASE OF VALIDATED PATIENT-REPORTED INSTRUMENTS

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Background: Over time, a patient-centered evaluation of health status has become more important for systemic sclerosis (SSc), both in research and clinical setting. Patient-reported outcomes (PROs) are being increasingly used to measure various domains of disease status relevant to patients and physicians. The EULAR Outcome Measures Library (OML) is a freely available website with structured access to a growing database of validated PROs [1], but currently there are no PROs available on SSc at the EULAR OML.
Objectives: To provide a comprehensive review of validated SSc-specific PROs and to critically appraise their validity.
Methods: A sensitive search was developed in Medline and Embase (08/2015) to identify all validation studies, cohort studies, reviews or metaanalyses in which the objective were the development or validation of PROs evaluating organ involvement, disease activity or damage in SSc. A reviewer screened title and abstracts, selected the studies, and collected data concerning validation using ad hoc forms based on the COSMIN checklist.
Results: From 13,140 articles captured, 74 met the predefined criteria. After excluding an instrument for the unavailability of an English version, the selected studies provided information on 6 SSc-specific PROs: the Scleroderma Assessment Questionnaire (SAQ), the scleroderma functional score (FS), the Raynaud's condition score (RCS), the Mouth Handicap in SSc (MHISS), the University of California Los Angeles-Scleroderma Clinical Trial Consortium Gastro-Intestinal tract (UCLA-SCTC-GIT 2.0), and the Skin Self-Assessment. The table summarizes the instruments and their measurement properties:

Table 1

SSc-specific PROs	Domains	No. of items and range	Measurement properties			
			Reliability IC/TR/ME	Validity	Responsiveness	Interpretability
SAQ	Functional status (vascular, respiratory, GIT and musculoskeletal apparatus)	Items: 23Range: 0–3	ICC 0.79–0.95	Total score higher in pts with systemic involvement	Vascular z=0.92–2.97; Respiratory z=1.34–2.52; GIT z=−3.14–4.03; Musculoskeletal status z=0.68–3.16	–
FS	Functional ability (upper limbs & muscle weakness)	Items: 11Range: 0–33	Intra-observk$_w$ 0.19–0.6inter-observk$_w$0.69–0.94	HAQ-DI r=0.90Skin score r=0.11	FS correlates with HAQ-DI 0.59, & Hand HAQ-DI 0.58	–
RCS	Severity and impact of Raynaud's phenomenon	Item: 1Range 0–10	ICC 0.70	Disease activity, Rp measures, digital ulcers, mood/tension 67% variance	ES 0.6SRM 0.64	MID 14–15 points (0–100 VAS)PASS 34 points
MHISS	Disability	Items:	ICC 0.96	HAQ	–	–

	involving the mouth	12Range: 0–48		r=0.33, CHFS r=0.37, mouth opening r=−0.34, MACTAR r=0.11, HADd r=0.26, HADa r=0.17		
UCLA SCTC GIT 2.0	GIT symptoms severity	Items: 34Range: 0–3	Cronbach's α>0.70, constipation (α=0.67)ICC 0.71	Total GIT score r=0.60; Upper GIT r=0.52; Lower GIT r=0.60	rho 0.05–0.48	MID/improvement: 0.07–0.36;MID/worsening: 0.06 −0.21;Floor: noneCeiling: 4%
Skin self-assessment	Skin thickening	Items: 17Range: 0–51	ICC 0.5–0.61	Skin score r=0.435	No changes 1 yr follow-up	– dcSScFloor <15%Ceiling <15%– lcSScFloor >15%Ceiling n.a.

Conclusions: Six SSc-specific PROs have a minimum validation and will be included in the EULAR OML. In general, the level of validation attained could be improved. Further development in the area of disease-specific PROs in SSc is warranted.

References:

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