PASTUL questionnaire: a tool for self-assessment of scleroderma skin during the COVID-19 pandemic

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COVID-19 pandemic heralds the biggest challenge faced by health services worldwide and remote consultations are now widely implemented. Evaluation of skin involvement with modified Rodnan Skin Score (mRSS) is central in systemic sclerosis (SSc) as it is associated with internal organ manifestations and mortality, and an increase in mRSS requires attention in all SSc subsets [1]. To monitor skin activity remotely during this pandemic we developed the PASTUL (Patient self-Assessment of Skin Thickness in Upper Limb) questionnaire. The questionnaire specifies a grading of skin (normal (0), mild (1), moderate (2), severely (3) thickened) at eight sites corresponding to mRSS with maximum score assigned to each site [2].

We evaluated the PASTUL questionnaire on feasibility and validity in SSc patients who had either a remote or face-to-face appointment at the Royal Free Hospital London, United Kingdom. Informed consent was obtained, and patient instructions were provided.
Scleroderma Skin Patient reported Outcome (SSPRO) [3], Scleroderma Health Assessment Disability Index (SHAQ-DI) [4], the Scleroderma Functional Score (SFS) [5] and the mRSS were collected to evaluate construct validity. The mRSS was done by an experienced rheumatologist without referring to the self-assessed score. Content validity was evaluated in a subgroup of patients by scoring relevance, clarity and practical difficulty of the PASTUL questionnaire on a 5-point Likert scale using ©Surveymonkey software. Patients were also asked to do the assessment two weeks later and to record the time required to complete the self-assessment. Data were analysed using SPSS 25 (IBM). Construct validity was evaluated using Pearson's correlation coefficient. Test-retest reliability was estimated using intraclass correlation coefficient (ICC). Coefficients were interpreted as follows: 0-0.19 = negligible, 0.2-0.39 = weak, 0.4-0.59 = moderate, 0.6-0.79 = strong, 0.8-1.0 = very strong.

130 patients were invited of which 104 (80%) completed all questionnaires. Mean age of participants was 57years (SD 12), 87% was female, 55 (53%) had limited cutaneous systemic sclerosis (lcSSc) and 49 (47%) diffuse cutaneous systemic sclerosis (dcSSc). PASTUL was completed by patients (86%) or a partner/relative (14%). For characteristics see online supplementary Table S1. Mean PASTUL score was 11 (SD 7), SHAQ 1.41 (SD 0.77), SFS 12.8 (SD 8.5) and SSPRO 48 (SD 27). PASTUL strongly correlated with total SSPRO and SSPRO subdomain physical limitations

(r=0.60 and 0.62, respectively). 78 (75%) patients completed mRSS. PASTUL and mRSS total and mRSS of upper limbs were moderately correlated (r=0.56 and 0.58, respectively). Table 1 shows the correlations of PASTUL scores with other outcome measures.

Similar approaches have been reported of physician-directed mRSS and patients' assessment of full mRSS [6]. Here, we refined this approach with a simplified instrument scoring only the upper limbs but still demonstrated good correlations with key outcome measures. Interestingly, correlation between PASTUL and mRSS was stronger in lcSSc compared to dcSSc (r=0.53 vs 0.43) and when assessed by a partner/relative compared to patients themselves (r=0.90 vs 0.54). Test-retest reliability, assessed in 21 patients, was excellent (ICC of 0.93, $p<0.001$). Participants (N=21) scored relevance with a mean score of 4.0 out of 5.0 (SD 1.0), clarity of instructions 4.3 out of 5.0 (SD 0.7) and practicability with 4.1 out of 5.0 (SD 0.9). The mean time to do the self-assessment was 4 minutes (SD 3).

As the pandemic continues, we need new ways to assess skin activity in our SSc patients. Correlations with SSPRO and mRSS support usefulness of PASTUL as an outcome measure. Moreover, our questionnaire empowers patients to help us delivering safe and effective care. Further research is needed to validate the PASTUL questionnaire in other groups, assess responsiveness, explore the role partners in assessment of skin and ways to implement PASTUL in daily practice.

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Table 1. Correlation of PASTUL score with other scleroderma outcome measures

Outcome measure	Pearson's correlation coefficient	P-value
mRSS	0.56	<0.001
mRSS upper limbs	0.58	<0.001
SHAQ-DI	0.38	<0.001
SHAQ VAS scores		
- VAS pain	0.28	0.107
- VAS GI	0.10	0.239
- VAS breathing	0.17	0.236
- VAS RP	0.16	0.406
- VAS DU	0.26	0.466
- VAS Limitations	0.32	0.026
SFS	0.25	0.011
SSPRO	0.60	<0.001
SSPRO subdomains		
- Physical effects	0.59	<0.001
- Physical limitations	0.62	<0.001
- Emotional effects	0.48	<0.001
- Social effects	0.42	<0.001

DU, digital ulcers; GI, gastrointestinal; mRSS, modified Rodnan Skin Score; PASTUL, Patient self-Assessment of Skin Thickness in Upper Limb; RP, Raynaud's Phenomenon; SFS, Scleroderma functional score; SD, standard deviation; SHAQ-DI, Scleroderma Health Assessment Questionnaire Disability Index; SSPRO, Scleroderma Skin Patient-Reported Outcome; VAS, visual analogue score