



Factors related to alexithymia in patients with systemic sclerosis: a tight relationship with facial image dissatisfaction

Fabio Basta¹ · Domenico Paolo Emanuele Margiotta² · Carmen Mazzuca² · Veronica Batani² · Giulio Dolcini² · Patrizio Moras² · Marta Vadacca² · Antonella Afeltra²

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Abstract

To assess clinical and psychosocial factors related to alexithymia in systemic sclerosis (SSc). We enrolled 40 consecutive SSc patients in a cross-sectional study evaluating alexithymia with Toronto Alexithymia scale (TAS-20). We measured Beck Depression inventory (BDI), Hamilton Anxiety rating scale (HAM-H), 36-Items Short-Form Healthy Survey (SF-36), Functional Assessment of Chronic Illness Therapy (FACIT)—Fatigue, Visual Analog Scale (VAS) pain, Pittsburgh Sleep Quality Index (PSQI), Satisfaction with Appearance Scale (SWAP), and Mouth Handicap in Systemic Sclerosis (MHSS). The prevalence of alexithymia was 42%. Alexithymic patients presented increased depressive ($p \leq 0.001$) and anxiety symptoms ($p \leq 0.001$), sleep disorders ($p = 0.03$), pain ($p = 0.02$), esthetic concerns ($p = 0.03$), disability in activities ($p = 0.03$) and reduced scores of SF-36 in mental components summary (MCS) ($p \leq 0.001$) and physical components summary (PCS) ($p = 0.01$). We found significant correlations with sleep disorders ($r = 0.41$, $p \leq 0.001$), BID ($r = 0.35$, $p = 0.04$), facial image dissatisfaction ($r = 0.35$, $p = 0.04$), mouth disability ($r = 0.51$, $p = 0.005$), depressive ($r = 0.6$, $p \leq 0.001$), and anxiety symptoms ($r = 0.48$, $p \leq 0.001$), fatigue ($r = -0.45$, $p = 0.005$), SF-36 PCS ($r = -0.51$, $p \leq 0.001$) and MCS ($r = -0.65$, $p \leq 0.001$). In multiple linear regression analysis, SWAP facial was the only variable associated with TAS-20 [0.99 (0.48) $p = 0.05$]. Alexithymia correlates with several psychosocial factors but seems strongly related to facial image dissatisfaction.

Keywords Systemic sclerosis · Alexithymia · Depression · Anxiety · Pain · QoL

✉ Fabio Basta
fabiobasta@libero.it

Domenico Paolo Emanuele Margiotta
d.margiotta@unicampus.it

Carmen Mazzuca
c.mazzuca@unicampus.it

Veronica Batani
v.batani@yahoo.it

Giulio Dolcini
dolcinigiulio@gmail.com

Patrizio Moras
moraspatrizio@gmail.com

Marta Vadacca
m.vadacca@unicampus.it

Antonella Afeltra
a.afeltra@unicampus.it

¹ Division of Rheumatology, IRCCS Ospedale Pediatrico Bambino Gesù, Piazza Sant'Onofrio, 4, 00165 Rome, Italy

² Unit of Allergology, Immunology and Rheumatology, Campus Bio-Medico University of Rome, Via Alvaro del Portillo 200, 00128 Rome, Italy

Introduction

Alexithymia describes the difficulties of people in identifying, differentiating and articulating emotions and in discriminating those from bodily sensations. Alexithymic patients have a limited imaginary capacity and a preference for externally oriented thinking rather than introspection [1], usually reporting high rates of concomitant depression and pain perception [2]. A high prevalence of alexithymia has been found in patients with a variety of chronic health conditions and in few rheumatological diseases, including fibromyalgia [3], rheumatoid arthritis (RA) and systemic lupus erythematosus (SLE) [4], with a prevalence ranging from 15 to 52% according to different studies. In these patients, the alexithymic trait was closely related with pain and depression whether a negative correlation has been found with quality of life and illness perception [5].

Systemic sclerosis (SSc) is a chronic disabling disease often burdened by severe physical and psychological impairment. Many patients affected by SSc must cope

with a progressive condition often characterized by pain, fatigue [6], disability and disfigurement [7]. These conditions can lead to psychological impairments, such as depression and anxiety, further affecting health-related quality of life (HRQoL) and even limiting social interactions [8]. The aforementioned aspects have been extensively investigated by several authors but, to our knowledge, no data were so far reported on the prevalence and the correlates of alexithymia among SSc patients. The aim of our study was, therefore, to assess the interplay between alexithymia and clinical and psychosocial factors related to the disease. We hypothesized that some recurrent complaints previously reported in SSc, such as mood disorders, pain and body image dissatisfaction (BID), could be correlated with alexithymia, leading to an overall impairment of HRQoL.

Methods

Study population

All patients were enrolled from the University Campus Bio-Medico of Rome and had a diagnosis of SSc based on the American College of Rheumatology/European League Against Rheumatism (ACR/EULAR) 2013 criteria [9]. The exclusion criteria were ongoing therapy for mood disorders and current mood disorders and/or other psychiatric disorders diagnosed by a neurologist or a psychiatrist. The study complied with the Declaration of Helsinki and was approved by the University Campus Bio-Medico Ethic Committee (48/18 OSS ComEt CBM). All patients signed an informed consent prior to be enrolled. During the recruitment, all patients underwent iloprost intravenous therapy, with an average of 6 h per course. Each patient was asked to complete all paper questionnaires during a single infusion, in a discrete and comfortable setting. When required, patients were helped in the comprehension of the questionnaires by at least one of the coauthors.

Sample size calculation

For sample size calculation and power analysis, we considered data concerning alexithymia previously reported in SLE patients [4]. Setting a significance level of 0.05 (α), power at 80% (β), an expected proportion of 0.3, and a total weight of confidence intervals of 0.2, we estimated a sample size of 38 subjects to assess the confidence intervals for proportion. Sample size calculation and power analysis were performed using SAS University Edition, SAS Institute Inc., SAS Campus Drive, Cary, North Carolina 27,513, USA.

Evaluation of socio-demographic aspects and disease features

Data concerning socio-demographic aspects (marital status, education level, employment status) were collected using a structured questionnaire. We evaluated SSc disease subtypes, disease duration, disease activity using European Scleroderma Study Group (ESSG) index [10] and disease severity using the Medsger's disease severity scale [11].

Evaluation of alexithymia

We assessed alexithymia with a self-measuring questionnaire, the Italian translation of the revised 20-item Toronto Alexithymia Scale (TAS-20) [12]. The TAS-20 score was analyzed as a continuous variable or as a categorical factor. Patients with $TAS \geq 61$ were considered as alexithymic [13]; patients with TAS between 51 and 60 were considered as moderate alexithymic; patients with $TAS < 50$ were considered as not alexithymic. The TAS-20 includes three subscales reported as continuous variables: difficulty identifying feelings (DIF), difficulty describing feelings (DDF) and externally oriented thinking (EOT) [14].

Evaluation of QoL, pain, fatigue, and sleep quality

Health-related Quality of Life (HRQoL) was assessed by the Italian version of Medical Outcomes Study (MOS) 36-Item Short-Form Healthy Survey (SF-36) (score range 0–100) [15]. To evaluate fatigue, we used the Italian version of The Functional Assessment of Chronic Illness Therapy (FACIT)—Fatigue (score range 0–52 lower scores meaning increased levels of fatigue) [16]. Pain was evaluated by the visual analog scale for pain (score range 0–10). Sleep quality was evaluated by the Pittsburgh Sleep Quality Index (PSQI) (score range 0–21 lower scores denoting a healthier sleep quality, cut-off 5) [17].

Evaluation of psychosocial aspects

Depressive symptoms were assessed with the Beck Depression inventory (BDI) (score range 0–63) [18] and anxiety symptoms were evaluated by the Hamilton Anxiety rating scale (HAM-H) (score range 0–56) [19]. Coping strategies in relation to stressful and difficult events were assessed with the Coping Orientation to Problems Experienced-New Italian Version (COPE-NIV), a 60-item self-report questionnaire exploring the following dimensions: Social Support (SS), Avoidance Strategies (AS), Positive Attitude (PA), Problem Solving (PS) and Transcendent Orientation (TO). Each item can be answered on

a four-point Likert-type scale ranging from “not at all” to “very much”. High scores obtained from each of the subscales give information about a separate coping attitude [20]. Body image dissatisfaction (BDI) was assessed using the Satisfaction with Appearance Scale (SWAP), a 14-item measure divided into four subscales: Social Distress (SD), Facial Features, Non-Facial Features, and Perceived Social Impact (PSI). The scores for the Facial Feature and Non-Facial Feature subscales can range from 0 to 24 and scores for the SD and PSI subscales can range from 0 to 18. Total scores can range from 0 to 84. Higher scores indicate greater BID [21].

Evaluation of patient disability

Disease-specific global disability was assessed with the scleroderma health assessment questionnaire (SHAQ), consisting of five patient-generated VAS added to the original HAQ, assessing Raynaud’s phenomenon, digital tip ulcers, gastrointestinal and lung symptoms, and overall disease severity from the patient’s perspective [22]. Mouth disability was assessed by the Mouth Handicap in Systemic Sclerosis (MHISS), consisting of 12 items (each scored 0–4, with a total score ranging from 0 to 48) divided into three subscales: subscale 1 assessing handicap related to reduced mouth opening, subscale 2 examining handicap related to Sicca syndrome, subscale 3 evaluating esthetic concerns [23]. Hand mobility for movements part of daily occupation was assessed by Italian version of Hand Mobility in Scleroderma Test (HAMIS), a performance-based test, composed of nine items (each scored 0–3), with a total score for both hands ranging from 0 to 54. Higher scores indicate greater hand disability [24].

Statistical analysis

Data were expressed as the median and interquartile range (IQR). Continuous variables were tested with the Kolmogorov–Smirnov test for normality. Differences between two independent groups were determined using the nonparametric Mann–Whitney *U* test. Categorical variables were analyzed using Fisher exact test. Correlation analysis was performed using the Spearman Test. Variables with significant association with TAS-20 and to DIF, DDF and EOT subscales were included in the multivariable linear regression models. The models were tested for multi-collinearity. Significance level adopted was two-tailed $p < 0.05$. All statistical analyses were performed with SAS University Edition, SAS Institute Inc., SAS Campus Drive, Cary, North Carolina 27,513, USA.

Results

Sample demographic and SSc-related features

We recruited 40 SSc female patients. The median age of the sample (interquartile range) was 62 (22) years and the disease duration was 6.5 (6.5). Fifteen (37.5%) patients had limited cutaneous systemic sclerosis (lSSc), whereas 25 (62.5%) had diffuse cutaneous systemic sclerosis (dSSc).

Alexithymic construct prevalence

The median value of the TAS-20 was 58 (20). The median values of TAS-20 subscales were: DIF 21 (11), DDF 16 (8) and EOT 20 (5).

The prevalence of alexithymic construct (patients with TAS-20 ≥ 61) was 42% (17 patients out of 40). Another five patients (13%) presented a TAS-20 score in the borderline range between 50 and 60 points.

Analysis of variables in relation to the presence alexithymic construct

Alexithymic patients had more severe depressive ($p \leq 0.001$) and anxiety symptoms ($p \leq 0.001$), increased pain ($p = 0.02$) and higher scores of sleep disorders ($p = 0.03$). Furthermore, they presented a significant reduction of SF-36 in both mental component summary (MCS) ($p \leq 0.001$) and physical component summary (PCS) ($p = 0.01$), also reporting increased aesthetic concerns ($p = 0.03$) and disability in home activities ($p = 0.03$). We did not find significant differences according to the presence of alexithymic construct and age, fatigue, BID, hand impairment, coping strategies and clinical factors such as disease severity, subtype, activity and duration. We reported in Table 1 the results of comparisons of continuous variables according to the presence of alexithymia.

Correlation analysis of variables associated with TAS-20 scale and subscales

According to Spearman’s analysis, there was a significant direct correlation between alexithymia and scores of sleep disorders, BID, facial image dissatisfaction, mouth disability, avoidance strategies, depressive and anxiety symptoms. A significant inverse correlation was also recorded with QoL and fatigue. In Table 2, we reported the results of correlation analysis of variables associated with TAS-20 scale and subscales.

Table 1 Comparisons of continuous variables according to the presence/absence of alexithymia (Mann–Whitney *U* test)

Parameter	TAS ≥ 61 Median (IQR)	TAS < 61 Median (IQR)	<i>p</i>
Age	62 (22)	62 (20)	0.66
Disease duration	6.5 (6.5)	4.5 (4)	0.55
Mean ESSG index	1 (1)	1 (2)	0.82
Medsger general	0 (1)	0 (1)	0.92
Medsger PV	1 (1)	1 (1)	0.85
Medsger skin	1 (1)	1 (1)	0.1
Medsger joint/tendon	0.5 (1)	0.5 (1)	0.6
Medsger muscle	0 (2)	0 (2)	0.78
Medsger GI tract	0 (1)	0 (1)	0.88
Medsger lung	1 (1)	1 (1)	0.44
Medsger heart	0 (0)	0 (0)	0.70
Medsger kidney	0 (0)	0 (0)	0.21
BDI score	22.5 (14)	8 (10)	≤ 0.001
HAM-H score	23 (14)	13 (19)	≤ 0.001
PSQI score	10.5 (7)	6 (4)	0.03
FACIT-fatigue	27 (9)	36 (19)	0.07
VAS pain	6 (2)	4 (4)	0.02
SF-36 MCS	31 (16.8)	67.7 (40.5)	≤ 0.001
SF-36 PCS	22.5 (20.9)	50.3 (44.1)	0.01
SWAP total	42 (11)	42 (8)	0.79
SWAP facial	10 (8)	11 (8)	0.32
SWAP non-facial	16 (9)	14 (12)	0.27
SWAP social distress	9 (11.5)	12 (10)	0.28
SWAP SPI	6 (11.5)	5 (10)	0.49
MHISS total	36 (38)	22.5 (16)	0.07
MHISS subscale 1 RMO	13 (5)	9 (5)	0.26
MHISS subscale 2 SS	12 (2)	8.5 (2)	0.07
MHISS subscale 3 AC	6 (3)	2.5 (4)	0.03
HAMIS total	11 (14)	10 (16)	0.96
COPE NIV total	140 (13)	127.5 (22)	0.52
COPE social support	27 (4)	23.5 (4)	0.57
COPE AS	27 (9)	23.5 (7)	0.20
COPE PA	29 (14)	31.5 (9)	0.89
COPE TO	24 (3)	24 (9)	0.52
SHAQ dressing	1 (2)	1 (1)	0.23
SHAQ arising	1 (2)	0 (1)	0.57
SHAQ eating	1 (0)	0 (1.5)	0.23
SHAQ walking	1 (2)	0 (1)	0.27
SHAQ hygiene	1 (2)	0 (0.5)	0.13
SHAQ reach	1 (1)	1 (2)	0.20
SHAQ grip	1 (2)	0.5 (1)	0.57
SHAQ activities	2 (1)	2 (2)	0.03
SHAQ disability index	1.25 (1)	0.5 (1.06)	0.10

TAS-20 20-item Toronto Alexithymia Scale, IQR Interquartile Range, ESSG European Scleroderma Study Group, PV peripheral vascular, GI gastrointestinal, BDI Beck Depression inventory, HAM-H Hamilton Anxiety rating scale, PSQI Pittsburgh Sleep Quality Index, FACIT Functional Assessment of Chronic Illness Therapy, VAS visual analog scale, SF-36 36-Item Short-Form Healthy Survey, PCS physical component summary, MCS mental component summary, SWAP Satisfaction with Appearance Scale, SPI Social Perceived Impact, MHISS Mouth Handicap in Systemic Sclerosis, RMO Reduced Mouth Opening, SS Sicca syndrome, AC Aesthetic Concerns, HAMIS Hand

Table 1 (continued)

Mobility in Scleroderma Test, COPE-NIV Coping Orientation to Problems Experienced-New Italian Version, PA Positive Attitude, AS Avoiding Strategies, TO Transcendent Orientation, SHAQ Scleroderma Health Assessment Questionnaire

Multiple linear regression analysis of variables associated with the TAS-20 scale and subscales

In the multiple linear regression analysis, we created a causal model assuming that BDI, HAM, MHISS and SWAP facial could have influenced TAS-20 scale and subscales. SWAP facial was the only variable significantly associated with TAS-20 ($p = 0.05$) and EOT subscale ($p = 0.02$) (Table 3).

Discussion

Alexithymia is a common finding in SSc, as it was present in more than 40% of our patients. No relation was found with SSc clinical aspects, such as disease subtype, disease duration, disease activity and disease severity. These data were largely expected, since we know that alexithymia is a psychopathological construct commonly developing as a reaction to stressful situation as the acceptance and coping with illness, more than relating to a specific disease or some specific clinical manifestations. Nevertheless, it must be pointed out that in SSc the extension of skin involvement is often associated with more severe disease and psychological burden [25]. Indeed, despite no association with skin involvement, we found a significant correlation between alexithymia and esthetic concerns, dissatisfaction with self-appearance and mouth disability, to symbolize the great contribution exerted by facial changes on the psychological health of SSc patients. Low functional status, considering some HAQ subscales pertaining to hand function such as eating, reach and activities, well correlated with alexithymia. On the contrary, hand mobility assessed by HAMIS, indicating the ability to use the hand in daily occupations, was poorly related to alexithymia.

As expected, we found a tight relationship between alexithymia and mood disorders, mainly depressive symptoms. Our data are in accordance with a recent meta-analysis of 19 studies showing that alexithymia, and in particular DIF and DDF, is closely related to depression [26]. Similarly, we were not surprised by the strong association found with pain perception, as we know that alexithymia can lead to dysregulated attention to bodily processes and somatosensory amplification [2, 4]. In addition, alexithymic patients reported impaired sleep disorders and increased fatigue. As known, those factors are often connected and reciprocally influenced by depression, as in a vicious circle [27]. We can speculate assuming that depression and, therefore, alexithymia lead

Table 2 Spearman’s correlation analysis of variables associated with the TAS-20 scale and subscales

Variable	TAS-20 total score		DIF sub-score		DDF sub-score		EOT sub-score	
	<i>r</i>	<i>p</i>	<i>r</i>	<i>p</i>	<i>r</i>	<i>p</i>	<i>r</i>	<i>p</i>
BDI score	0.6	<0.0001	0.63	<0.0001	0.37	0.03		
HAM-H score	0.48	<0.0001	0.44	<0.0001				
FACIT-fatigue score			− 0.45	0.005			− 0.43	0.006
PSQI score	0.41	<0.0001	0.36	0.02			0.46	0.006
SWAP total	0.35	0.04					0.34	0.05
SWAP facial	0.35	0.04					0.37	0.03
MHISS total	0.51	0.005	0.47	0.01			0.42	0.02
MHISS subscale 1 RMO	0.43	0.02	0.38	0.04			0.36	0.05
MHISS subscale 2 SS	0.44	0.01	0.39	0.04			0.38	0.04
MHISS subscale 3 AC	0.5	0.006	0.54	0.002			0.38	0.04
SHAQ disability index							0.33	0.03
SHAQ activities							0.35	0.03
SHAQ reach							0.35	0.02
SHAQ eating							0.4	0.01
COPE-NIV AS			0.51	0.006				
SF-36 MCS	− 0.65	<0.0001	− 0.63	0.001	− 0.45	0.01	− 0.56	0.001
SF-36 PCS	− 0.51	<0.0001	− 0.45	0.009			− 0.53	0.002
SF-36 PF	− 0.49	0.004					− 0.51	0.002
SF-36 RP							− 0.49	0.004
SF-36 BP	− 0.42	0.01	− 0.43	0.01			− 0.51	0.002
SF-36 GH	− 0.35	0.04	− 0.41	0.01				
SF-36 VT	− 0.54	<0.0001	− 0.51	0.001			− 0.55	0.001
SF-36 SF	− 0.60	<0.0001	− 0.6	<0.0001	− 0.40	0.02	− 0.5	0.004
SF-36 RE	− 0.42	0.01	− 0.34	0.05			− 0.41	0.01
SF-36 MH	− 0.78	<0.0001	− 0.78	<0.0001	− 0.52	0.002	− 0.41	0.02

TAS-20 20-item Toronto Alexithymia Scale, DIF difficulty identifying feelings, DDF difficulty describing feelings, EOT externally oriented thinking, BDI Beck Depression Inventory, HAM-H Hamilton Anxiety Rating Scale, FACIT Functional Assessment of Chronic Illness Therapy, PSQI Pittsburgh Sleep Quality Index, SWAP Satisfaction with Appearance Scale, MHISS Mouth Handicap in Systemic Sclerosis, RMO Reduced Mouth Opening, SS Sicca syndrome, AC Aesthetic Concerns, SHAQ Scleroderma Health Assessment Questionnaire, COPE-NIV Coping Orientation to Problems Experienced-New Italian Version, AS Avoiding Strategies, SF-36 36-Item Short-Form Healthy Survey, MCS mental component summary, PCS physical component summary, PF Physical Function, RP Role Physical, BP Bodily Pain, GH Global Health, VT Vitality, SF Social Function, RE Role Emotional, MH Mental Health

Table 3 Multiple linear regression analysis of variables associated with the TAS-20 scale and subscales

Variable	TAS-20 total score		DIF sub-score		DDF sub-score		EOT sub-score	
	<i>B</i> (SE)	<i>p</i>	<i>B</i> (SE)	<i>p</i>	<i>B</i> (SE)	<i>p</i>	<i>B</i> (SE)	<i>p</i>
BDI score	0.46 (0.44)	0.29	0.21 (0.14)	0.35	0.31 (0.16)	0.43	− 0.13 (0.17)	0.44
HAM-H score	0.01 (0.32)	0.97	0.17 (0.15)	0.26	0.09 (0.1)	0.57	0.2 (0.12)	0.11
SWAP facial	0.99 (0.48)	0.05	0.54 (0.23)	0.08	0.28 (0.18)	0.09	0.47 (0.18)	0.02
MHISS total	− 0.24 (0.34)	0.48	− 0.17 (0.21)	0.31	− 0.21 (0.28)	0.65	− 0.10 (0.13)	0.46

TAS-20 20-item Toronto Alexithymia Scale, DIF difficulty identifying feelings, DDF difficulty describing feelings, EOT externally oriented thinking, SE standard error, BDI Beck Depression Inventory, HAM-H Hamilton Anxiety Rating Scale, SWAP Satisfaction with Appearance Scale, MHISS Mouth Handicap in Systemic Sclerosis

to impairment of sleep quality and increased fatigue. On the other hand, sleep disorders could reverberate this circuit worsening depression and alexithymia, overall making it

more difficult for the patient to take charge of the disease. In this regard, our finding on the relationship between alexithymia and increased adoption of avoidance coping strategies

among SSc patients is interesting. The dysfunctionality of alexithymic process in the emotion processing and in adoption of effective coping strategy, widely demonstrated in previous reports, leads to further psychological distress [28, 29]. As an overall consequence, in our study alexithymic patients presented a strong impairment of quality of life, concerning both PCS and MCS.

The different behavior found in our study between DIF and DDF, closely associated with depressive symptoms, compared to EOT, instead characterized by a stronger relationship with BID, has been already reported in literature [25] and is explicative data underlying the importance of EOT, as cognitive component of TAS probably more decisive in processing emotions.

Moreover, our results suggest that alexithymia could be associated with several psychosocial factors related to SSc. Whereas in other rheumatological conditions the relationship with depression was the predominant feature, the multivariable models seem suggest that the pivotal component associated with the presence of alexithymic in SSc patients is the facial distress. As a matter of fact, BID mainly due to visible changes in face and hands is consistently related with symptoms of anxiety and depression, and leads to social discomfort especially for younger patients, who are commonly more willing to meet new people and to develop intimate relationships [30, 31].

We can hypothesize that, with the increasing of the emotional burden related to SSc (due to prognostic uncertainty, depression, pain, disability but most of all to BID), then the dysfunctionality of alexithymic construct emerged, leading to an overall impairment of HRQoL. Conversely, the negative role exerted by alexithymia in facing stressful situations could have amplified the psychological distress related to the disease, more specifically increasing facial image dissatisfaction.

Our study presents strengths and limitations. It was the first to assess the prevalence of alexithymia in SSc aiming to give an overall description of the phenomenon. As a matter of fact, we performed a wide evaluation of clinical and psychosocial factors potentially involved in alexithymia, also using linear regression analysis to identify factors independently related to TAS-20 and each subscale. On the contrary, the strongest limitations of our study were the absence of a healthy and a disease control group and the small sample size, which could have limited the statistical significance of some associations, as well as reducing the power of multivariate analysis. Last, some patients were helped in the comprehension of the questionnaires. Therefore, they could have been influenced in the filling of TAS-20, which depends on the comprehension of the subject.

We need a greater accumulation of evidence to better define alexithymia in SSc, to evaluate the effectiveness of alexithymia treatment and its possible favorable impact on

several psychosocial outcomes. A more careful assessment of alexithymia in daily clinical practice could be considered in patients with a strong suspicion of psychological distress. Tailored interventions could be also considered, especially in patients with high levels of alexithymia.

Alexithymia is a common finding in SSc patients, correlated with several psychosocial factors. By multivariate analysis, facial image dissatisfaction resulted as the only factor significantly associated with alexithymia.

Author contributions FB was responsible for conceptualization, methodology, data collection, data curation, literature review and article writing. DPEM was responsible for methodology, data curation and formal analysis. CM, VB, GD and PM were responsible for data collection. MV was responsible for literature review, writing and review. AA was responsible for conceptualization, writing, reviewing and editing.

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Compliance with ethical standards

Conflict of interest Fabio Basta declares he has no conflict of interest, Domenico Paolo Emanuele Margiotta declares he has no conflict of interest, Carmen Mazzuca declares she has no conflict of interest, Veronica Batani declares she has no conflict of interest, Giulio Dolcini declares he has no conflict of interest, Patrizio Moras declares he has no conflict of interest, Marta Vadacca declares she has no conflict of interest, and Antonella Afeltra declares she has no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee, and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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