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Psychopathological symptoms and their association with the quality of life and the sexual functioning in women affected by systemic scleroderma: a preliminary investigation

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Abstract. – OBJECTIVE: This study aimed to investigate the presence of psychopathological symptoms and the relations of these dimensions with the quality of life and sexual function in a group of women affected by systemic scleroderma.

SUBJECTS AND METHODS: Seventy-one women with systemic scleroderma were invited to participate in the study; 65 agreed to participate, while 6 declined. Four questionnaires were administered to the patients: a specific socio-demographic questionnaire, the Symptom Checklist-90-Revised (SCL-90-R), the Female Sexual Function Index (FSFI), and the Quality-of-Life Questionnaire of the European Foundation for Osteoporosis (QUALEFFO-41).

RESULTS: Of all the participants in this study, 48% of patients showed a clinical score on SCL-90-R Somatization, 45% on depression, and 37% on obsessive-compulsive. As hypothesized, psychopathological symptoms were related to lower quality of life since somatization and depression predicted the total score of health-related quality of life and lower sexual functions, showing a specific effect of depression on sexuality.

CONCLUSIONS: Our findings highlighted the presence of an association between psychopathological symptoms and reduced sexual functioning and the associations between somatization and the health-related quality of life dimensions in scleroderma patients. Furthermore, our results sustain the importance of also considering the mental health of patients with systemic sclerosis, within an integrated biopsychosocial care model.

Key Words:
Systemic scleroderma, Systemic sclerosis, Psychopathological symptoms, Quality of life, Sexual functions.

Introduction

Systemic scleroderma or systemic sclerosis (SSc) is a rare multisystem connective tissue disease affecting the skin and joints, as well as internal organs, including the heart, lungs, kidneys and gastrointestinal tract[1]. This rare disease presents two peak incidence periods: the first between the ages of 7 and 10 and the second and most common, between 40 and 50, with a ratio range of 3:1-4:1, with a female preponderance[1-3].

The word "scleroderma" derives from two Greek words, "skleros" meaning hard, and "derma," meaning skin[4]; therefore, reflecting the disfiguring elements of the disease, including skin thickening to the hands and face[5]. The disease course can vary substantially: for some, it might remain mild for years, whereas in others, it might progress rapidly with damage to internal organs, leading to death within months of diagnosis[5]. Symptomatic treatment of SSc includes both non-pharmacological interventions, such as manual lymph drainage and physiotherapy, as well as assistance from pharmacological agents[1].

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Treatments are used to manage symptoms, but there is no cure[5].

Patients with SSc experience multiple pain symptoms that impair their functional activities and daily life, the most common being joint pain, localized musculoskeletal aches, dyspnea and dysphagia, gastrointestinal and digestive pain, and digital ulcers[6]. These patients often experience elevated symptoms of psychological distress, determined by changes in physical appearance, pain, fatigue sensation, and difficulty in daily life occupations[7]. All of these changes can further have a high impact on an individual's health-related quality of life and may lead to depressive symptoms[5,8,9]. SSc's more severe symptoms were associated with a poorer quality of life and depression, functional disability, and fatigue[10-12]. In Müller et al[1], 69% of the sample were screened for positive symptoms of depression, with the quality-of-life impairment and female sex emerging as independent risk factors for depressive symptoms. In the Thombs et al[13] review, it has been reported that 36% to 65% of patients experienced significant depressive symptoms. These results are comparable to or higher rates among patients with other chronic diseases. According to Baubet et al[14], the rate of major depressive disorder in scleroderma is 19%.

Different studies[15,16] identify depressive symptoms as the most common psychological symptoms in the SSc population, highlighting how the prevalence of depression in patients with SSc is significantly higher than in the general population.

In their narrative review, Mura et al[7] reported that the mental health of patients with SSc is significantly impaired and that psychiatric symptoms are frequent in these patients. However, pain, fatigue, disability, and bodily changes do not appear to explain the high prevalence of psychiatric comorbidity in patients with SSc.

Angelopoulos et al[17] found that compared to healthy women, patients suffering from SSc reported significantly higher depression, anxiety, somatization, interpersonal sensitivity, and obsessive-compulsive symptoms. Paranoid ideation and psychotic symptom scores were also higher in the clinical sample than in the control group. The authors[17] concluded that psychiatric symptomatology in the form of anxiety, depression, obsessive-compulsiveness, somatization, and feelings of guilt were reported by the majority of patients with scleroderma.

In a recent review, Nakayama et al[18] highlighted that SSc is an illness that undermines patients' sense of certainty and control and impairs self-image, identity, and daily functioning. Furthermore, these patients contend with an uncertain prognosis and seem to feel isolated by the rarity of the disease. Physical changes and consequent self-rejection lead some to withdraw into themselves, which consequently places a strain on their relationships and intimacy with their partner[18]. More specifically regarding sexuality, international literature[19-21] shows that SSc affects normal sexual functioning, sexual desire, satisfaction, and frequency of intercourse. It has been hypothesized[22] that in patients with SSc, sexual function is closely linked to depressive symptoms. In fact, it is known that emotional well-being plays an important role in sexual functioning and that patients who suffer from sexual dysfunction are more likely to have depressive symptomatology[23].

In conclusion, SSc is a rare disease associated with a poorer health-related quality of life and depressive symptoms. The prevalence of psychiatric symptoms in patients with scleroderma and their association with sexual function and quality of life, although a matter of clinical interest, is rather poorly studied[16,17].

The principal aim of the present study is to investigate the presence of psychopathological symptoms and the relation of these dimensions with the quality of life and sexual function in a group of women affected by scleroderma. Specifically, the present study aims to explore possible differences in health-related quality of life and sexual function scores between groups of women, showing a score under/over the clinical cut-off in the psychopathological dimensions. It has been hypothesized that groups of women reporting higher psychopathological symptoms will also show higher levels of sexual dysfunction and lower levels of health-related quality of life.

In this study, we also test the possible predictive effect of these psychopathological dimensions and of age, on the health-related quality of life and sexual function of women with scleroderma.

Subjects and Methods

The present investigation is an observational study that was conducted from July 2022 to September 2022. The present investigation has been approved by the local Ethical Committee Lazio 2 (IRB protocol number: 0128753/2022).

Informed consent regarding the research use of participants' medical information was obtained from all individual participants included in the study, in accordance with local and international legislation (Declaration of Helsinki).

Participants were recruited from patients who were consequently admitted to the Department of Vascular Medicine and Autoimmunity at Sandro Pertini Hospital in Rome, Italy. Participants were screened by a physician to determine the eligibility of the women during their clinical visit. Inclusion criteria included patients who were:

- suffering from scleroderma (for at least one year);
- female;
- between the ages of 30 and 60;
- adequately understanding of the Italian language.

We excluded women with an inadequate understanding of the Italian language and/or with a history of a psychiatric disorder. For the evaluation of this last criterion, the women's declaration of having received a diagnosis of psychiatric disorders and/or using pharmacological treatments for mental disorders has been taken into consideration. No women were excluded for this cause.

After the medical visit, the physician introduced the eligible women to the psychologist responsible for the research protocol implementation and the women who agreed to participate signed an informed consent before completing the tests. The whole research protocol took place in the medical center and was implemented by a qualified psychologist.

Seventy-one women were invited to participate in the study; 65 agreed to participate, while 6 declined. No woman was excluded for mental health problems since none had reported having suffered from psychiatric disorders or using drugs for their treatment in the anamnesis procedure or in the socio-anamnestic questionnaire. Non-participation was mainly due to time constraints. A total of 65 women were included in the research protocol, with a mean age of 44.71 years (SD = 11.96; age range 25-60) and a mean of 4.6 years of pathology (SD 2.7). Regarding the educational level, 12% of the participants reported having a lower secondary school education, 53% reported an upper secondary school education, and 35% reported a university-level education. Regarding social status, 60% were married/cohabitating/in a stable relationship, 33% were separated/divorced, and 7% were single. Regarding the employment status, 52% of the participants declared to be working/employed, 23% reported to work freelance, 15% reported being homemakers, and 10% reported being unemployed.

Measures

Socio-demographic questionnaire

A specific socio-demographic questionnaire was designed to collect information concerning age, social status, education level, and occupational activity.

Psychopathological symptoms

The Symptom Checklist-90-Revised (SCL-90-R)[24] is a 90-item self-report inventory that measures psychological and psychosomatic symptoms occurring in the last week. Each item is a description of a psycho-physical symptom and is rated by respondents on a five-point Likert scale (0-4) from having caused no discomfort to having caused extreme discomfort during the past week.

The SCL-90-R has 9 subscales: (1) Somatization, (2) Obsessive-Compulsive, (3) Interpersonal Sensitivity, (4) Depression, (5) Anxiety, (6) Hostility, (7) Phobic Anxiety, (8) Paranoid Ideation, and (9) Psychoticism. The sum of all 9 subscales is the Global Severity Index (GSI), which can be used as a summary of the test, reflecting overall psycho-physical distress. The SCL-90-R shows adequate test-retest reliability, internal consistency, and concurrent and discriminant validity. Cronbach's alpha of subscales in the present study ranged from .74 to .86.

Sexual Dysfunction

The Female Sexual Function Index (FSFI)[25,26] is a patient-reported outcome scale measuring female sexual (dys)-function based over the past 4 weeks. It is composed of a 19-item questionnaire organized in 6 separate domains of female sexual function, namely: (1) desire, (2) arousal, (3) lubrication, (4) orgasm, (5) satisfaction, and (6) pain. The score range for items 3 to 14 and 17 to 19 is between 0-5; and for items 1, 2, 15, and 16, the score ranges from 1-5. The total score range is from 2 to 36, with the higher scores indicating better sexual functioning. The FSFI showed a good internal consistency for all scales and acceptable test-retest reliability. Cronbach's alpha of subscales in the present study ranged from .76 to .84.

Health-Related Quality of Life

Quality of Life Questionnaire of the European Foundation for Osteoporosis (QUALEF-

FO-41)[27,28] is a self-administered questionnaire composed of 41 items divided into five domains: (1) pain (2) physical function (3), social function (4), general health perception, and (5) mental function. Most of the items have 5-answer options, with the exceptions of items No. 23, 24, 25, and 26, which have 3-answer options, and items No. 27, 28, and 29 with 4-answer options. Items are scored in the reverse order (the minimum number on the scale is assigned to the best answer and the maximum to the worst answer), except for items No. 33, 34, 35, 37, 39, and 40. The score of each domain is calculated as an average value of all the answered items linearly transformed on a scale of 0-100. The total score is calculated as a sum of all answers to items and then linearly transformed on a scale of 0-100. The worse the health-related quality of life is, the higher the score gets. The test showed good internal consistency and test-retest reliability. Cronbach's alpha ranged from 0.72 to 0.80 in the present study.

Statistical Analysis

All statistical analyses were executed using the Statistical Package for Social Science version 25 for Windows (SPSS version 25; IBM., Armonk, NY, USA). Data was reported as frequency and percentage for discrete variables and as means and standard deviations for continuous variables.

One-way ANOVAs were performed to evaluate possible differences in health-related quality of life and sexual function in groups of women with a score over/under the clinical cut-off of 1 in the psychopathological dimensions. A series of multiple linear regression models were performed to explore the predictive effect of the clinical psychopathological dimensions and age (independent variables) on health-related quality of life and sexual function (dependent variables). All independent variables were entered simultaneously. Statistical significance was considered when $p < .05$.

Results

Table I shows the mean score obtained for the test administered. Furthermore, the percentage of women obtaining a score ≥ the clinical cut-off of 1 in the SCL-90 R psycho-

Table I. Socio-demographic and psychological characteristics of the sample.

Variables	M	SD	
FSFI total	15.83	13.05	
Desire	2.74	1.30	
Arousal	2.89	2.19	
Lubrication	2.66	2.40	
Orgasm	2.60	2.42	
Satisfaction	2.63	2.45	
Pain	2.92	2.61	
QUALEFFO-41 total	31.70	18.03	
Pain	27.30	24.54	
Physical function	19.43	18.29	
Social function	38.38	28.32	
General health perception	59.61	24.12	
Mental Function	43.20	22.64	
			% participant with a score ≥ clinical cut off 1
SCL-90 R Global Severity Index	0.79	0,72	25%
Somatization	1.04	0,72	**48%**
Obsessive-Compulsive	0.85	0,79	**37%**
Interpersonal Sensitivity	0.70	0,75	29%
Depression	0.92	0,74	**45%**
Anxiety	0.67	0,58	20%
Hostility	0.52	0,63	13%
Phobic Anxiety	0.34	0,64	15%
Paranoid Ideation	0.63	0,70	23%
Psychoticism	0.47	0,65	13%

FSFI = Female Sexual Function Index; QUALEFFO-41 = Quality of Life Questionnaire of the European Foundation for Osteoporosis-41; SCL-90 R = Symptom Checklist-90-Revised.

Table II. Differences between group of women with a score < / ≥ the clinical cut-off in the three most representative psychopathological dimensions.

SCL-90 R Somatization	Clinical N = 34		Not clinical N = 31		F	p
	M	**SD**	**M**	**SD**		
FSFI total	19.44	13.61	12.64	11.88	4.020	**0.05**
Desire	3.22	1.28	2.40	1.21	6.241	**0.01**
Arousal	3.52	2.09	2.31	2.17	4.605	**0.03**
Lubrication	3.32	2.59	2.03	2.04	4.288	**0.04**
Orgasm	3.14	2.60	2.20	2.15	2.376	0.12
Satisfaction	3.18	2.65	2.23	2.20	2.299	0.13
Pain	3.65	2.77	2.26	2.19	4.743	**0.03**
QUALEFFO-41 total	21.40	12.18	42.40	16.10	32.743	**0.001**
Pain	16.94	16.61	37.59	27.01	12.906	**0.001**
Physical function	10.86	11.04	28.16	19.05	18.814	**0.001**
Social function	25.22	21.24	51.80	28.51	16.908	**0.001**
General health perception	46.77	23.34	73.56	17.54	24.982	**0.001**
Mental Function	32.52	19.90	54.79	19.94	18.705	**0.001**
SCL-90 R Depression	**Clinical N = 36**		**Not clinical N = 29**			
FSFI total	21.43	12.31	10.18	11.55	12.569	**0.001**
Desire	3.26	1.06	2.33	1.39	8.035	**0.006**
Arousal	3.83	1.99	1.93	2.01	12.761	**0.001**
Lubrication	3.71	2.36	1.55	1.92	13.991	**0.001**
Orgasm	3.42	2.35	1.80	2.29	6.871	**0.01**
Satisfaction	3.62	2.42	1.67	2.15	10.233	**0.002**
Pain	4.06	2.46	1.68	2.18	14.747	**0.001**
QUALEFFO-41 total	22.41	13.43	42.70	15.73	29.045	**0.001**
Pain	23.93	22.66	30.55	26.32	1.094	**0.300**
Physical function	12.70	12.03	27.19	18.64	11.903	**0.001**
Social function	24.72	21.31	54.37	27.23	22.380	**0.000**
General health perception	48.98	24.36	72.83	17.84	17.965	**0.000**
Mental Function	29.29	16.48	60.39	16.74	51.766	**0.000**
SCL-90 R Obsessive-Compulsive	**Clinical N = 40**		**Not clinical N = 25**			
FSFI total	18.81	13.25	11.80	9.00	4.069	**0.04**
Desire	3.13	1.22	2.31	1.30	5.749	**0.02**
Arousal	3.42	2.15	2.14	2.07	4.947	**0.03**
Lubrication	3.31	2.57	1.69	1.55	6.787	**0.01**
Orgasm	2.97	2.51	2.16	2.03	1.484	0.22
Satisfaction	3.20	2.58	2.05	1.21	2.499	0.12
Pain	3.44	2.69	2.14	2.03	3.484	**0.06**
QUALEFFO-41 total	24.21	13.60	44.20	16.78	25.307	**0.001**
Pain	21.71	20.14	35.90	28.68	5.045	**0.03**
Physical function	13.32	12.80	29.41	20.28	14.271	**0.001**
Social function	28.78	22.83	54.10	29.80	13.661	**0.001**
General health perception	51.09	23.42	74.62	19.15	15.969	**0.001**
Mental Function	33.84	18.35	59.60	20.40	25.262	**0.001**

FSFI = Female Sexual Function Index; QUALEFFO-41 = Quality of Life Questionnaire of the European Foundation for Osteoporosis-41; SCL-90 R = Symptom Checklist-90-Revised.

pathological dimensions and Global Symptoms Inventory (GSI) was reported, highlighting that Somatization (48% of the whole sample in the clinical range), Depression (45% of the sample in the clinical range), and Obsessive-Compulsive scales (37% of the whole sample in the clinical range) are respectively the most represented psychopathological symptoms reported (Table I).

Table II shows differences between groups of women with scores under and over the clinical cut-off in the three most representative psychopathological dimensions (Somatization, Depression, and Obsessive-Compulsive scales),

highlighting several significant differences. Generally, as hypothesized, psychopathological symptoms were related to lower quality of life and lower sexual functions.

A set of multiple linear regression analyses was performed using, respectively, the QUALEFFO-41 and FSFI total scores as dependent variables and SCL-90-R Somatization, Depression, and Obsessive-Compulsive dimensions and age as independent variables. The first model explained that 52% of the QUALEFFO-41 total score ($R^2 = 0.52$; adjusted $R^2 = 0.49$) indicated an adequate fit of the model tested. The independent variable that showed a significant effect was Somatization (beta = 0.614; $p < .001$). The second model tested to show possible predictive effects of these psychopathological dimensions and age on the FSFI total score did not show any significance. Due to the significance of the first model tested, and in order to deeply investigate the role of somatization, depression, obsessive-compulsive symptoms, and age on specific features of health-related quality of life, the regression analysis was repeated using the QUALLEFFO-41 dimensions as dependent variables. Regarding the "Pain" dimension, the model explained that 35% of the total score of the QUALEFFO-41 ($R^2 = 0.35$; adjusted $R^2 = 0.31$) indicated an adequate fit of the model tested. The independent variables that showed a significant effect were Somatization (beta = 0.724; $p < .001$) and Depression (beta = -0.742; $p < .002$). Regarding the "Physical Function" dimension, the model explained that 33% of the total score of the QUALEFFO-41 ($R^2 = 0.33$; adjusted $R^2 = 0.30$) indicated an adequate fit of the model tested. The independent variable that showed a significant effect was Somatization (beta = 0.569; $p < .001$). Regarding the "Social Function" dimension, the model explained that 34% of the total score of the QUALEFFO-41 ($R^2 = 0.34$; adjusted $R^2 = 0.31$) indicated an adequate fit of the model tested. The independent variable that showed a significant effect was Somatization (beta = 0.502; $p < .001$). Regarding the "General Health Perception" dimension, the model explained that 43% of the total score of the QUALEFFO-41 ($R^2 = 0.43$; adjusted $R^2 = 0.40$) indicated an adequate fit of the model tested. The independent variable that showed a significant effect was Somatization (beta = 0.588; $p < .001$). Regarding the "Mental Function" dimension, the model explained that 60% of the total score of the QUALEFFO-41 ($R^2 = 0.60$; adjusted $R^2 = 0.58$) indicated an adequate fit of the model tested. The independent variable that showed a significant effect was Depression (beta = 0.642; $p < .001$).

Discussion

The present study aimed to investigate the prevalence of psychopathological symptoms in a group of women affected by Systemic Sclerosis, also exploring the association between psychological dimensions, health-related quality of life, and sexual function. According to the SCL-90 R clinical cut-offs, the most represented clinical dimensions were a) Somatization, with 48% of patients obtaining a score in the pathological range; b) Depression, with 45% of the sample in the pathological range; c) Obsessive-Compulsive, with 37% of patients in the pathological range. Specifically, regarding these dimensions, it should be noted that in the international literature on SSc cohorts, the only one widely investigated is depression. In fact, several studies[1,13-16,29-32] focused on depressive symptoms in SSc patients, finding that the rate of depression ranges from 16% to 69%. Inadequate investigations are reported regarding other psychopathological dimensions, such as Somatization and Obsessive-Compulsive dimensions. In fact, to the authors' knowledge, in the international literature, only two studies[17,33] emerged regarding SSc patients. According to a Greek study[17], SSc patients report significantly higher scores in somatization than the general population. According to an Indian study[33], patients with SSc report 15% higher scores of obsessive-compulsive disorders (OCD), a percentage that is 20 times greater than that reported in the general Indian population. Somatization can be defined as the "tendency to experience and communicate psychological distress in the form of physical symptoms and to seek medical help for them"[34] regardless of whether the nature of the symptoms is medically explained or not. Moreover, according to the DSM-5[35], the current definition of Somatic Symptom Disorder is based on the presence of one or more somatic symptoms that are distressing or resulting in significant disruption of daily life, with excessive thoughts, feelings, or behaviors related to the somatic symptoms or associated health concerns. Therefore, it is not required that the somatic symptoms are medically unexplained. In the international literature, the bidirectional interaction between emotions and

physical well-being is widely recognized[36]. In this light, psychoneuroimmunology supports the contribution that negative emotions can have on the dysregulation of the immune system[37]. Moreover, psychological impairment is negatively associated with adherence level of medication and therapies in different medical conditions[38].

Further, regarding the differences in health-related quality of life and sexual functioning between groups of women showing a score under/over the clinical cut-off in the three most represented psychopathological dimensions, several significances in the hypothesized direction emerged. Specifically, patients in the psychopathological range scored higher in the sexual functions test (indicating less sexual satisfaction) and lower in the health-related quality of life, compared to those with scores in the normal range. Regarding the health-related quality of life, differences between groups emerged in all the considered dimensions, whereas, for sexual functioning, the FSFI Orgasm and Lubrication scales appeared to be statistically different only when comparing groups over/under the clinical cut-off for Depression, but not for Somatization and Obsessive-Compulsive symptom scores. Thus, it may be hypothesized that depressive symptomatology is mostly affecting the sexuality of these clinical populations. This result appeared to be in line with the findings of a systematic review[39] highlighting the bidirectional association between depression and sexual dysfunction. More specifically, adults with depression had a 50-70% increased risk of developing sexual dysfunction, and those with sexual dysfunction had a 130-210% increased risk of developing depression[39]. However, more generally, it seems possible to sustain the presence of an association between psychopathological symptoms and reduced sexual function in SSc patients, which is in line with the broader literature[22,23] highlighting the role of emotional and psychological aspects in the complex area of sexuality.

Through the regression analysis, the predictive effect of Somatization and Depression on health-related quality of life (total and dimensions) emerged. More specifically, Somatization was a significant predictor for all the health-related dimensions evaluated, except for Mental Function, whereas Depression predicted Pain and Mental Function.

The associations between somatization and the health-related quality of life dimensions in SSc patients found in the present study appeared to confirm the findings reported by Hyphantis et al[40] on this topic. It is interesting that the Mental Function dimension was only positively predicted by depression and that depression showed a negative predictive effect on the pain dimension. It may be hypothesized that depression and somatization represent two different and opposite means to experience and express emotional distress: one on physical health (somatization) and one on mental health (depression). This is consistent with a psychoanalytic view on somatization, as according to Bucci's Multiple Code Theory, sustaining that somatization can be considered to be a consequence of a dissociation between the visceral – pre-symbolic system and the symbolic and verbal systems, thereby affecting normal emotional processing[36,41].

Contrary to the study's hypothesis, a predictive effect of depressive, somatic, and obsessive-compulsive symptomatology on sexual functioning did not emerge.

Limitations

Several limitations should be considered in interpreting these results. First, the reduced sample size is partially due to the specific clinical sample investigated. Second, the use of self-report measures, and in this direction, future studies with multimethod assessment should be realized[42]. Third, the cross-sectional design of the study hinders the possibility of drawing causal conclusions from the observed relationships. Fourth, the absence of a control group, both with the general population and other clinical populations, which should be considered in further studies.

Conclusions

Within the context of these limitations, our findings highlighted the role of somatization in SSc patients that should be further explored in future studies. Furthermore, the findings seemed to confirm the role of depression in this population. Our results, therefore, sustain the importance of also considering the mental health of patients with systemic sclerosis within an integrated biopsychosocial care model. Clinicians should pay attention to both the physical symptoms due to rheumatic disease and the possible psychopathological symptoms. For this reason, a multidisciplinary model of care can include psychological counseling to support SSc patients in promoting their mental and physical quality of life.

Conflict of Interest
The Authors declare that they have no conflict of interest.

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Ethics Approval
The present study has been approved by the local Ethical Committee Lazio 2 (IRB protocol number: 0128753/2022).

Authors' Contributions
All authors contributed substantially to the work reported and have read and agreed to the published version of the manuscript.

Informed Consent
Informed consent was obtained from all individual participants included in the study.

Data Availability
Data are available on request from the corresponding author.

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