
Sexual function in German women with systemic sclerosis compared to women with systemic lupus erythematosus and evaluation of a screening test

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ABSTRACT

Objective. To assess and compare sexual dysfunction (SDF) in female patients with systemic sclerosis (SSc) or systemic lupus erythematosus (SLE), to correlate sexual function with disease characteristics and depression, and to evaluate a short questionnaire (Qualisex) as a screening test.

Methods. Female patients with systemic sclerosis or systemic lupus erythematosus in two German tertiary university hospitals were evaluated in a prospective study. A self-designed questionnaire, the Female Sexual Function Index (FSFI), the Qualisex, and the Beck's depression inventory were used.

Results. 171 female patients were included into the study (83 with SSc, and 88 with SLE). 62.6% (52 of 83) of SSc patients and 67.0% (59 of 88) of SLE patients were sexually active. Only 9.6% of SSc patients and 14.8% of SLE patients had ever discussed sexual problems with their physician. Significantly more SSc patients would wish to discuss sexuality with their physician more intensively (37.3% vs. 28.4% in SLE patients, $p=0.011$). Among the 51 sexually active and evaluable SSc patients a mean FSFI of 25.53 (± 5.06) was found, with a FSFI value defining sexual dysfunction (SDF) (<26.55) in 49% of patients, which did not differ significantly compared to SLE patients ($n=59$, mean FSFI 26.92 (± 5.17), SDF in 45.8%). The Qualisex correlated significantly with the FSFI, and both Qualisex and FSFI correlated with depressiveness.

Conclusion. Sexual dysfunction (SDF) is a frequent problem in female patients with SSc and SLE. Addressing sexual issues during medical consultation is an unmet need. The Qualisex constitutes a short questionnaire, which is suitable for addressing concerns on sexuality.

Introduction

Systemic sclerosis (SSc) and systemic lupus erythematosus (SLE) are two heterogeneous connective tissue diseases with significant morbidity and mortality (1, 2). The majority of patients are women, and several manifestations of both diseases can cause impairment of function in daily life including sexual function in female patients. There are common disease characteristics and comorbidities in SSc and SLE in this respect, like fatigue, joint pain, or depression. Nevertheless, manifestations of SSc and SLE differ considerably. In SSc, skin tightening of hands and lips, joint contractures, or vaginal sclerosis may severely impair sexual function. In SLE, stigmatising rashes, pleurisy, and neuropathy may play a role.

Most studies on sexual impairment in SSc and SLE assess sexual dysfunction (SDF) in patients of only one disease entity; some compare a selected patient population to the general population, and a wide range of SDF prevalence is described in the literature (3-5).

The Female Sexual Function Index (FSFI) is designed as a very detailed questionnaire on several aspects of sexual function mainly used in studies, whereas the Qualisex is a shorter questionnaire with less intimate questions on the influence of the respective disease on sexual function, on the patient's wellbeing in general, and on his or her partnership respectively, and was validated for female patients with rheumatoid arthritis (6).

To our knowledge, there is no published data on the evaluation of sexual impairment in female patients with SSc or SLE in German populations, and no study compared disease-specific factors influencing sexual impairment between women with SSc and women with SLE.

Competing interests: none declared.

Furthermore, no practical tests suitable to assess sexual function in an everyday clinical setting were used or validated in studies on these diseases. Thus the objectives of this study were 1) to compare sexual impairment in female patients between SSc and SLE, 2) to assess the need for counselling on sexual function related to these diseases, 3) to investigate the influence of depressiveness on sexual dysfunction, and 4) to evaluate the Qualisex as a test for sexual impairment in SSc and SLE.

Materials and methods

Female patients with systemic sclerosis or systemic lupus erythematosus in two German tertiary university hospitals were evaluated with a self-designed questionnaire on various sexual and gynaecological aspects, a 19-item version of the Female Sexual Function Index (FSFI), the 10-item questionnaire Qualisex, and the Beck's depression inventory in a prospective study.

Ethics statement

Ethics approval for the present study was obtained from the Ethics committee of both Tübingen University and Würzburg University (project no. 708/2015BO2). All patients provided informed written consent. Patients were informed explicitly about the anonymous handling of data, and that not even their treating physician or the study physician would be able to link their questionnaires on sexuality with their personal data, to exclude influence on the questionnaire results by embarrassment.

Patients

Female patients were recruited during their regular rheumatological visits at the outpatient department in two tertiary university hospitals (Tübingen and Würzburg), if they had a rheumatologist-confirmed diagnosis of SSc or SLE, and were ≥ 18 years old. Patients were excluded if they had another disease which would impair sexual function, e.g. pelvic radiation.

Questionnaires

Female Sexual Function Index (FSFI)

A 19-item version of the FSFI was used, which assesses desire, arousal, satis-

faction, lubrication, orgasm, and pain on vaginal penetration. The maximum score would be 36 with higher scores indicating less sexual impairment (7).

Definition of sexual dysfunction (SDF) using FSFI

SDF was defined by a FSFI score of <26.55 in sexually active women according to Rosen *et al.* (8).

Qualisex

The Qualisex is a 10-item questionnaire, which was validated as a screening test for SDF in a French rheumatoid arthritis population (4), and modified by exchanging the terms of disease entities. The questions relate to the influence of general health, rheumatic disease, rheumatic medication, pain, and health on sexuality, partnership, and the feeling of being attractive. The score ranges from 0 to 10 with higher scores indicating more sexual impairment.

Beck's Depression Inventory (BDI)

The BDI contains 21 questions on symptoms of depression: a score of 10 to 16 would be compatible with mild depression, a score of 17 to 29 with moderate depression, and a score of more than 29 up to the maximum score of 63 would be compatible with severe depression (9).

Self-designed questionnaire

A self-designed questionnaire with 18 questions (see supplementary material S1) assessed age, marital status, land of origin, smoking habit, social background, number of children and pregnancies, frequency of sexual intercourse, disease-specific and non-disease-specific reasons for sexual impairment, hormonal status, age of first sexual intercourse, and the influence of disease onset on sexuality. Patients were specifically asked if or if not they had certain reasons for sexual impairment, *i.e.* impaired pelvic mobility, mucosal dryness, painful sexual intercourse, or vaginal stenosis. They could also specify other reasons. Furthermore, patients were asked if sexuality was discussed with their physician, if they thought that sexuality was relevant to their disease, and if they wished to discuss sexual

impairment with their physician more. This questionnaire was created to cover aspects of sexualisation and sexuality, which would not be mentioned in the standard questionnaires.

Clinical characteristics

The following clinical characteristics were assessed: disease entity and subgroup, age of disease onset, disease duration, organ and musculoskeletal involvement, and anti-rheumatic medication (for definitions of organ involvement see Supplementary file S2).

Statistical analysis

For descriptive analysis mean values $\pm$ standard deviation for metric variables and percentages for categorical variables were calculated. Mean values of metric variables were compared using the t-test for independent samples. To compare categorical variables, Pearson's Chi-squared test was used. Contingency tables were calculated with Yates's correction. With frequencies of five or lower Fisher's exact test was applied.

The association of FSFI and Qualisex was assessed with Spearman's correlation coefficient, after asserting that both variables were not distributed normally by graphic depiction and QQ-plot.

Results

Sample characteristics

171 female patients were included into the study. Among them 83 suffered from SSc (mean age 48.50 years), and 88 from SLE (mean age 39.65 years). In SSc patients, 39.8% had a diffuse cutaneous form, and 47% were anti-topoisomerase antibodies (Scl70) positive. Organ involvement (Table I) and immunosuppressive medication were frequent in both groups. 61.4% of SSc patients, and 84.1% of SLE patients received DMARDs or immunosuppressive medication apart from anti-malarials. 34.9% of SSc patients and 28.4% of SLE patients ever received cyclophosphamide. 44.6% of SSc patients and 87.5% of SLE patients took glucocorticoids (Table I). Disease duration was significantly longer in SLE patients (13.17 vs. 9.85 years in SSc patients, $p=0.021$). More SSc patients had children (68.7% vs. 50%, $p=0.020$). No

significant differences between SSc and SLE were found as to educational background, BDI depression categories, marital status, or number of children.

Assessment of sexuality issues during routine clinical care

Only 9.6% of SSc patients and 14.8% of SLE patients had ever discussed sexual problems with their rheumatologist, although 52% of all patients thought that these were relevant in relation to their disease and wellbeing. Significantly more SSc patients would wish to discuss sexuality with their physician more intensively (37.3% vs. 28.4% in SLE patients, $p=0.011$).

Sexual activity and impairment in female patients with SSc or SLE

79.5% of SSc patients and 79.4% of SLE patients were in a constant relationship; 62.6% (52 of 83) of SSc patients and 67.0% (59 of 88) of SLE patients were sexually active. Frequency of sexual intercourse did not differ between SSc and SLE: once to twice per week in 56.6% vs. 59.1% of all patients, 3 to 4 times per week in 4.4% vs. 6.8%, and more than 4 times per week in 1.2% vs. 1.1% (Table II).

Reasons for not being sexually active did not differ significantly between SSc and SLE. 22.9% of SSc patients, and 20.5% of SLE patients stated that the rheumatic disease itself was that reason ($p=0.841$).

In relation to all sexually active patients, the most common disease-related impeding factors against sexual intercourse were vaginal sicca in 40.9%, pain in 28.1%, vaginal stenosis in 18.1%, and impaired mobility of pelvis in 17%. These Impeding factors did not differ significantly between SSc and SLE (Table III).

Prevalence of sexual dysfunction

Among the 51 sexually active and evaluable SSc patients a mean FSFI of 25.53 (± 5.06) was found, with a FSFI value below the cut-off defining SDF (<26.55) in 49% of patients, which did not differ significantly compared to SLE patients ($n=59$, mean FSFI 26.92 (± 5.17), SDF in 45.8%). Regarding the separate categories of the FSFI, only

Table I. Organ involvement and rheumatological medication in female patients with SSc and SLE.

SSc (n=83), mean age 48.5 years (± 11.07 SD), mean disease duration 9.85 years (± 8.40 SD)	
Skin involvement	83 (100%)
Involvement of joints and tendons	57 (68.7%)
Digital ulcers	46 (55.4%)
Gastrointestinal involvement	44 (53.0%)
Pulmonary involvement	43 (51.8%)
Cardiac involvement	13 (15.7%)
Pulmonary arterial hypertension	6 (7.2%)
Renal involvement	3 (3.6%)
Current immunosuppressive or DMARD other than antimalarials	61.4%
Current glucocorticoid treatment	44.6%
Ever received cyclophosphamide	34.9%
SLE (n=88); mean age 39.65 years (± 12.29 SD), mean disease duration 13.17 years (± 10.02 SD)	
Involvement of joints and tendons	67 (76.1%)
Skin involvement	67 (76.1%)
Cytopenia	46 (52.3%)
Renal involvement	38 (43.2%)
Involvement of central nervous system	15 (17.0%)
Current immunosuppressive or DMARD other than antimalarials	84.1%
Current glucocorticoid treatment	87.5%
Ever received cyclophosphamide	28.4%

SD: standard deviation.

Table II. Characteristics of sexuality, FSFI, Qualisex, rate of sexual dysfunction (SDF), BDI in female patients with SSc or SLE. FSFI, Qualisex, and BDI are presented as mean and SD. All parameters did not differ significantly.

	SSc patients (n=83)	SLE patients (n=88)
Sexually active	62.6% (52 of 83)	67.0% (59 of 88)
Sexual intercourses per week:		
1 to 2	56.6%	59.1
3 to 4	4.4%	6.8%
More than 4	1.2%	1.1%
FSFI (in sexually active patients)	25.53 (± 5.06) (51 of 52 evaluable)	26.92 (± 5.17) (59 of 59 evaluable)
SDF (FSFI <26.55)	49%	45.8%
Qualisex (in sexually active patients)	2.98 (± 2.24) (45 of 52 evaluable)	3.16 (± 2.45) (52 of 59 evaluable)
BDI (severity of depressiveness)	Of 79 evaluable SSc patients	Of 88 evaluable SLE patients:
10-16 (mild)	27 (32.5%)	25 (28.4%)
17-29 (moderate)	12 (14.5%)	25 (28.4%)
30-63 (severe)	5 (6.0%)	4 (4.5%)

the category libido showed a statistically significant difference between disease entities. SSc patients had a significantly lower mean FSFI-value for libido (2.65 ± 1.13) compared to SLE patients (3.14 ± 1.22 ; $p=0.008$). Statistical analysis was repeated within separate age groups, but was hampered by small sample sizes. In each age group mean FSFI and rate of SDF was not significantly different between SSc and SLE (Table IV).

Association of depression and sexual dysfunction

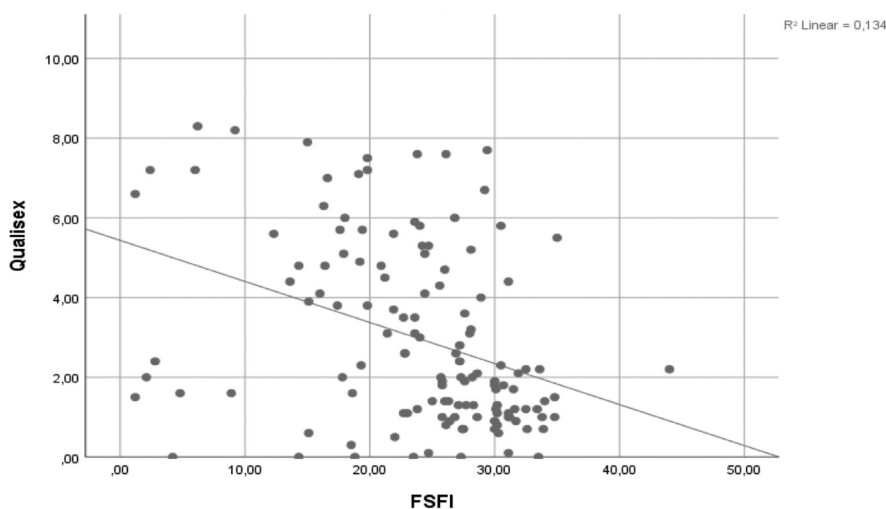
Depressive symptoms were assessed using the Beck's Depression Inventory (BDI). 30.4% of 171 evaluable patients had a score of 10 to 16 (compatible with mild depression), 21.6% had a score of 17-29 (compatible with moderate depression), and 5.3% a score of 30 or higher (compatible with severe depression). Regarding severity of depressive symptoms, no statistically significant

Table III. Frequency of patients with disease specific sexually impeding factors.

	SSc patients (n=83)	SLE patients (n=88)	p-value
Vaginal stenosis	14 (16.9%)	17 (19.3%)	0.678
Painful sexual intercourse	24 (28.9%)	24 (27.2%)	0.811
Vaginal dryness	36 (43.3%)	34 (38.6%)	0.529
Impairment of pelvic mobility	15 (18.1%)	14 (15.9%)	0.706
Other complaints: fatigue, dyspnea, vaginal itching, reduced libido, joint pain	8	8	

Table IV. Rates of sexual dysfunction (defined by FSFI <26.55) in sexually active women divided by age groups. FSFI is presented as mean $\pm$ standard deviation.

	SSc	SLE	p-value
All ages	n=51	n=59	
Mean FSFI	25.53 $\pm$ 5.06	26.92 $\pm$ 5.17	0.158
Patients with SDF	25 (49.0%)	27 (45.8%)	0.881
Age group 18-29	n=4	n=17	
Mean FSFI	24.28 $\pm$ 6.80	27.48 $\pm$ 4.56	0.261
Patients with SDF	2 (50.0%)	6 (35.3%)	0.618
Age group 30-39	n=13	n=16	
Mean FSFI	27.83 $\pm$ 3.62	27.84 $\pm$ 4.76	0.994
Patients with SDF	3 (23.1%)	6 (37.5%)	0.454
Age group $\geq$40	n=34	n=26	
Mean FSFI	24.80 $\pm$ 5.19	25.99 $\pm$ 5.78	0.405
Patients with SDF	20 (58.8%)	15 (57.7%)	>0.999

**Fig. 1.** Correlation of Qualisex and FSFI in all evaluable patients with SSc or SLE (Scatterplot).

difference was found between SSc and SLE patients. There was only a trend for a higher percentage of moderately depressive patients in SLE (28.4% vs. 14.5%, $p=0.062$).

More patients who suffered from SDF were at least mildly depressive defined by BDI (score of 10 or higher) than patients without SDF (71.2% vs. 46.4%, $p=0.016$).

Correlation of BDI, Qualisex and FSFI

SSc patients showed a numerically better Qualisex than SLE patients (2.98

(± 2.24) vs. 3.16 (± 2.45) with 0 meaning no impairment and 10 severe impairment). The Qualisex correlated significantly with the FSFI ($r=-0.390$; $p<0.001$) with numerically better correlation in SSc patients ($r=-0.451$, $p<0.001$ vs. $r=-0.342$, $p=0.003$), but correlation was low (Fig. 1).

Depressiveness measured by BDI correlated significantly with both FSFI and Qualisex in SSc and SLE patients respectively. In SSc patients, Spearman's rank correlation coefficient was -0.418 ($p=0.001$) for correlation between BDI

and FSFI, and 0.623 ($p<0.001$) between BDI and Qualisex, respectively. In SLE patients, Spearman's rank correlation coefficient was -0.364 ($p=0.002$) for correlation between BDI and FSFI, and 0.452 ($p<0.001$) between BDI and Qualisex, respectively. In both disease cohorts, BDI correlated better with Qualisex than with FSFI, and again correlation between BDI and Qualisex or FSFI was numerically higher in SSc patients than in SLE patients. Therefore the highest correlation coefficient was found for BDI and Qualisex in SSc patients (Fig. 2).

Discussion

This is the first study to compare sexual activity and sexual function between female patients with SSc and SLE in Germany.

Despite the university setting with research interest in sexual function and longer patient visits, the percentage of women who had ever discussed sexual issues with their physician was low (9.6% of SSc patients and 14.8% of SLE patients), although more than half of the patients thought that sexuality was relevant in relation to their disease, and more than a third of patients expressed the wish to discuss sexuality with their physician more intensively or at all (37.3% in SSc vs. 28.4% in SLE). It can only be speculated that outside this setting these rates might even be more unfavourable.

An unmet need of SSc and SLE patients to address sexual problems with their rheumatologist has been eloquently expressed by self-help groups in and outside Germany since many years (10, 11). Our study could confirm this need. 62.6% of SSc patients and 67.0% of SLE patients were sexually active. Sexual impairment was frequently caused by vaginal sicca, pain on sexual intercourse, vaginal stenosis or impaired mobility of pelvis. The frequency of disease-related reasons for impairment did not differ significantly between SSc and SLE. Therefore this study was not able to identify disease-specific reasons for impairment, and according to this finding, patients in routine care should rather not receive a focused assessment of sexuality according to disease entity,

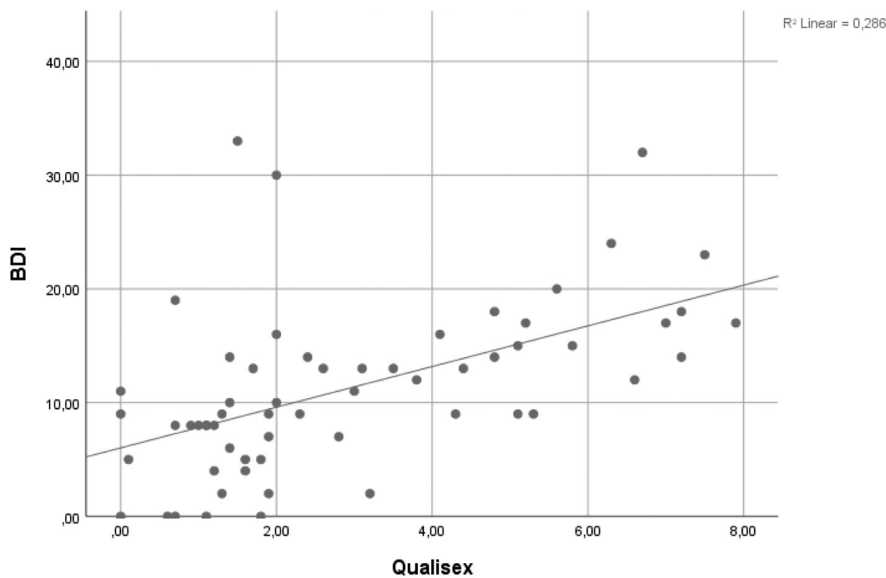


Fig. 2. Correlation of Qualisex and BDI in patients with SSc in all evaluable patients (Scatterplot).

but a rather general assessment is recommendable.

In both SSc and SLE nearly half of sexually active women suffered from sexual dysfunction (SDF) defined by a FSFI of <26.55 according to Rosen (6) (49% in SSc, and 45.8% in SLE). About two thirds of the patients were either not sexually active or had SDF (68.1% in SSc and 63.7% in SLE). It is quite remarkable that sexual impairment and dysfunction turned out to be quite similar in SSc and SLE respectively, although disease manifestation and mucocutaneous involvement are apparently so different, as was the case in our cohort.

The rates of sexual dysfunction are difficult to compare with those in the literature, since other studies also used different questionnaires to assess sexual function, other versions of the FSFI were used, or the FSFI cut-off for SDF was defined differently. These discrepancies also explain the wide range of SDF rates found in studies from different countries. In SSc patients, SDF rates from 32% up to 90% were reported in samples from North America (12–14), Italy (3), Tunisia (15), Brasil (16), and the Netherlands (16).

In SLE, SDF rates vary from 45.9% to 64.1% in studies from China (17), Spain (18) and Taiwan (19).

Ferreira *et al.* assessed sexual function in different rheumatic diseases including SSc, SLE, and fibromyalgia, and

found the highest FSFI-defined SDF rate in patients with SSc (33%) (20).

In essence, the SDF rates we found fall within the wide range of known literature about SSc and SLE.

There are several studies that evaluated sexual impairment using the FSFI in German women of the general population. The assessment of female German medical students showed a mean FSFI of $28.6 (\pm 4.5)$ and a prevalence of SDF of 32% with a FSFI of <26.55 (21). Other studies found a rate of SDF among 20- to 80-year-old German women of 32 to 38% (22, 23). Although this does not allow a matched comparison with our study population it becomes clear that SDF prevalence seems to be higher in our SSc and SLE patients compared to the general population.

Since sexual impairment is known to influence depression, and *vice versa*, Beck's Depression Inventory (BDI) was used to evaluate depressiveness in our patients, which did not differ significantly between SSc and SLE. Patients who suffered from SDF were more likely to have at least mild depression defined by BDI. In a Chinese study depression was identified as the main factor to influence sexual function in female SLE patients (24). Depressiveness measured by BDI was significantly correlated both with the FSFI and the Qualisex in our cohorts of SSc and SLE patients respectively, but correlation coefficients were rather low. Numerically

the best correlation was found between BDI and Qualisex in SSc patients. It may be speculated that the perception of functional and emotional aspects of sexuality is influenced by depressiveness in female SSc patients to a greater extent, or that the specific sexual impairments in SSc are more prone to lead to a depressive disorder. Accordingly, a higher prevalence of depression was found in SSc – particularly in diffuse cutaneous forms – compared to rheumatoid arthritis in a recent study (25).

One of the aims of this study was to evaluate the Qualisex as a more suitable screening test for routine care. The questionnaire was validated for a French rheumatoid arthritis cohort (4).

In 53 RA-patients (44 women, mean age 50.7 years) the mean score was 3.3 ± 2.5 , and the Qualisex results were correlated with disease activity and symptoms, but not with depression. In our study, the mean Qualisex score was even slightly lower (SSc: $2.98 (\pm 2.24)$; SLE: $3.16 (\pm 2.45)$), meaning less impairment, although our patient cohort – and the SSc patients in particular were not much younger (mean age SSc 48.50 years; SLE 39.65 years).

The Qualisex significantly correlated with the FSFI results in SLE and SSc patients. Nevertheless, the correlation coefficient was low, wherefore the Qualisex was not further validated as a diagnostic test for SDF in our cohort. The rather low correlation could be explained by the focus of the FSFI on physical aspects of sexual function, whereas the Qualisex comprises a broader and more emotional view on sexuality including questions on partnership and self-perception. The higher correlation of the Qualisex with BDI compared to FSFI with BDI in our patients would also underscore this hypothesis.

Our study has several limitations. Due to lack of a matched healthy control group, we cannot provide the risk of sexual impairment attributable to the chronic disease. Yet our main intention was to find disease-specific factors of sexual impairment; thus our study was planned to compare samples of SLE and SSc patients, which would be suitable for this primary objective.

Furthermore, our questionnaire was not designed to assess disease-related reasons for sexual impairment in a quantitative way. Thus, we could not identify whether there was a difference between the disease groups as far as the intensity of reasons for sexual impairment is concerned. Likewise organ involvement was not assessed in a quantitative way or according to disease stages, which would have allowed a more detailed analysis.

Our sample size was too small to adjust for age in a detailed analysis of SDF. Nevertheless, we compared SSc and SLE patients within different age groups and found no difference in mean FSFI and rate of SDF. Thus, the influence of age on our results should be negligible.

In summary, although sexual impairment and dysfunction constitutes a common problem in female patients with SSc and SLE, and our study found a remarkable unmet need in sexual counselling. Prevalence of sexual dysfunction and disease-specific impeding factors are comparable between female patients with SSc and SLE, respectively. The short practicable Qualisex questionnaire seems to be suitable to serve as a tool to address sexual issues in routine care of female SSc and SLE patients.

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