

Concise report

Frequency and impact of symptoms experienced by patients with systemic sclerosis: results from a Canadian National Survey

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Abstract

Objective. Knowledge about the range of symptoms experienced by patients with SSc, and their impact on daily functioning is limited. The objective of the present study was to identify symptoms of SSc that patients rated as frequent and that highly impacted their ability to carry out daily activities.

Methods. A total of 464 persons with SSc responded to the Canadian Scleroderma Patient Survey of Health Concerns and Research Priorities, including questions regarding the frequency and impact of 69 SSc symptoms. Descriptive analyses were performed dichotomizing symptom frequencies as never or rarely vs sometimes, most of the time or always and symptom impact on daily activities as no or minimal impact vs moderate to severe impact.

Results. The five highest rated symptoms in terms of frequency and moderate to severe impact on daily activities, respectively, were: fatigue (89 and 72%), RP (86 and 67%), hand stiffness (81 and 59%), joint pain (81 and 64%) and difficulty sleeping (76 and 59%). In addition to these symptoms, items related to decreased hand function (difficulty making a fist and difficulty holding objects) and pain (muscle pain and joint tenderness) were frequently endorsed and commonly associated with moderate to severe impact on daily activities.

Conclusion. This study confirmed the importance for quality of life of core symptoms of SSc, such as pain, fatigue and limitations in hand function. It also identified areas with very little research, such as sleep problems, that appear to play important roles in daily functioning, and that merit more focused study.

Key words: Systemic sclerosis, Scleroderma, Fatigue, Hand function, Sleep problems, Pruritus, Quality of life.

Introduction

SSc, or scleroderma, is a chronic, multi-system, connective tissue disorder characterized by thickening and

fibrosis of the skin, involvement of internal organs, and substantially reduced functional ability and quality of life (QoL) [1–3]. Patients with SSc report a number of problems associated with disability and reduced QoL, including gastrointestinal problems, difficulty breathing, pain from various sources, depression, fatigue and pruritus [4–11]. Due to the rarity and heterogeneity of the disease, however, not enough is known about the frequency and perceived impact of the range of problems faced by individuals living with SSc. There is also a lack of consensus on which problems should be the focus of research. Whereas physicians may prioritize objective indicators of disease status, patients may perceive other aspects of their disease experience as more debilitating or distressing [12].

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Submitted 21 June 2010; revised version accepted 19 August 2010.

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Several existing studies have assessed the degree to which specific SSc symptoms are prevalent, annoying or burdensome to patients [12–14]. van Lankveld *et al.* [13] administered an 18-item disease-related stressors questionnaire to 123 Dutch SSc patients using a 4-point Likert scale ranging from not annoying at all to very annoying and reported that fatigue, functional limitations, skin deformities, pain and disfigurement were among the most annoying symptoms. Richards *et al.* [14] assessed 14 symptoms among 49 patients in the UK and found that stiff joints, pain and fatigue were most commonly associated with SSc. Suarez-Almazor *et al.* [12] conducted focus groups with 19 patients in the USA and identified physical pain, coping skills, social aspects of living with the disease, physical appearance and patient–physician relationships as particularly important to patients. However, knowledge about the range of problems experienced by patients with SSc, and the relative importance of different problems, is limited by the small number of existing studies, the relatively narrow range of potential problems assessed in these studies and the small number of patients included in each study.

The Canadian Scleroderma Patient Survey of Health Concerns and Research Priorities was developed jointly by patients and researchers in order to assess topics of potential importance to patients that may currently be under-researched. The survey encompassed a wide range of topics, including health care accessibility and satisfaction, financial and employment implications of living with SSc and disease symptomatology. The objective of this study was to identify symptoms of SSc rated by patients as frequent or high impact in terms of reduced ability to carry out daily activities, in a large Canadian sample of persons with SSc.

Patients and methods

Patient sample

Persons with SSc were recruited to complete the anonymous survey from September 2008 to August 2009. The survey was publicized with a presentation at the annual meeting of the Scleroderma Society of Canada in September 2008; via notices posted on the web sites of the Scleroderma Society of Canada and Sclérodémie Québec; in full-page advertisements in Canadian magazines in English (McLean's) and French (l'Actualité); by announcements in Canadian national and provincial scleroderma-related newsletters; by contact with members of support groups across Canada by chapter leaders; and with promotional materials that were distributed in offices of physicians affiliated with the Canadian Scleroderma Research Group. Patients were able to complete the survey in English or French online using Survey Monkey, an easy to use web-based survey tool, or by requesting a paper copy. To be included in data analyses for the present study, survey respondents were required to be at least 18 years old, to have reported being diagnosed with SSc by a physician and to be a resident of Canada. In addition, patients who

failed to complete $\geq 10\%$ of survey items on symptom frequency and severity (14 of 138 items) were excluded.

Survey respondents did not provide signed informed consent due to the anonymous, confidential nature of the survey. The study was approved by the Research Ethics Board of McGill University. In addition, Canadian Scleroderma Research Group sites across Canada received ethical approval from their own research ethics committees to distribute promotional material related to the survey.

Patient survey

A panel of Canadian Scleroderma Research Group and Scleroderma Society of Canada members jointly developed the 36-page survey. Existing questionnaires, symptom checklists and research articles [12–16] were examined before creating the survey to ensure that the survey addressed as many potentially significant issues as possible. Prior surveys created by the Arthritis Society were consulted, including the Listening to Patients Survey [17] and the CARE III online patient survey [18]. In addition, a panel of clinicians, researchers and patients was consulted to develop survey sections and items and to provide feedback in order to refine and modify the survey. Drafts of the survey were piloted for content and structure by 25 Scleroderma Society of Canada patient members from across Canada.

A list of 69 symptom items was generated. Patients were asked to rate the frequency and impact of each symptom. The frequency questions were worded 'How frequently have you experienced (insert symptom) in the past year?' with the response options never, rarely, sometimes, most of the time and always. To determine the impact, participants were asked to 'Please specify the degree of impact that (insert symptom) has had on your ability to carry out everyday activities in the past year', with the response options no impact, minimal, moderate, severe and extremely severe. When frequency was rated never, impact was automatically coded no impact.

Data analyses

Symptom frequency and impact were recoded into dichotomous variables. With respect to frequency, responses were coded never or rarely vs sometimes, most of the time or always. For impact, responses were coded no impact or minimal impact vs moderate, severe or extremely severe impact. We performed a descriptive analysis of the frequency of symptoms rated as at least some of the time and symptom impact on daily activities rated as at least moderate. In addition, for each item, among patients with frequency of at least sometimes, the percentage of patients with at least moderate impact was calculated. For items on vaginal dryness and erectile dysfunction, only responses from women and men, respectively, were tabulated.

Results

Sample characteristics

A total of 856 surveys were completed, 669 (78%) online and 187 (22%) using the paper version. Of these, 64 (7%) were classified as likely duplicates, based on matching demographic data. This generally occurred when respondents began the online survey, submitted part of it and subsequently started again. Of the 792 unique persons who completed all or part of the survey, 153 (19%) were not eligible because the respondent did not report a diagnosis of SSc by a specific health care provider (e.g. rheumatologist, dermatologist), including 36 respondents with linear scleroderma or morphea; 8 (1%) were not eligible because the respondent was <18 years of age; 38 (5%) were not eligible because the respondent was not from Canada. Of the 603 potentially eligible surveys, 139 (23%) were excluded because patients completed <10% of symptom items. A total of 464 respondents were included in analyses.

Demographic characteristics of the present sample are presented in Table 1. Most respondents were females (88%), white (72%), primarily English speaking (77%), married (72%) and had at least a high school education (89%). The mean age was 56 years, and the mean time since diagnosis of SSc was 11 years. Approximately half

TABLE 1 Socio-demographic variables of survey respondents (n = 464)

Variables	
Female gender, n (%)	410 (88)
Age, mean (s.d.)	55.8 (12.9)
Race/ethnicity, n (%)	
White	336 (72)
Aboriginal	18 (4)
Asian	21 (5)
Black	3 (1)
Other	86 (19)
Level of education, n (%)	
Less than high school	49 (11)
High school graduate	291 (63)
University graduate	124 (27)
Marital status, n (%)	
Single	39 (8)
Married	332 (72)
Separated/divorced/widowed	93 (20)
Primary spoken language, n (%)	
English	355 (77)
French	109 (24)
Working (full time or part time), n (%)	146 (31)
Disease subtype, n (%)	
Diffuse	59 (13)
Limited/CREST	169 (36)
Sine	2 (<1)
Not known	234 (50)
Treated by rheumatologist, n (%)	291 (63)
Years since SSc diagnosis, mean (s.d.)	10.9 (9.4)

of respondents reported that they had diffuse (13%) or limited (36%) SSc, whereas half (50%) did not know their disease subtype classification.

Symptom frequency and impact on daily activities

Frequency and impact on daily activities for each symptom are shown in Table 2. The five most frequently experienced symptoms, all of which were endorsed by >75% of respondents, included fatigue (89%), RP (86%), hand stiffness (81%), joint pain (81%) and difficulty sleeping (76%). Symptoms related to pain and discomfort, including skin tightening (72%), muscle pain (71%) and tender joints (71%) were also endorsed by at least 70% of the respondents. In addition to hand stiffness, two other items related to the hands were endorsed at very high rates, difficulty making a fist (67%) and difficulty holding objects (67%).

The symptoms that were most frequently experienced also tended to be the symptoms that had at least moderate impact on daily activities. Several symptoms, however, were highly ranked in terms of frequency, but rated much lower in terms of impact, including itching, which was the 9th most frequently experienced, but 31st in terms of impact, dry mouth (13th vs 27th) and skin colour change (15th vs 42nd). On the other hand, open sores was ranked 55th in terms of frequency, but 32nd in terms of the number of patients with at least moderate impact.

Problems associated with SSc that had at least moderate impact among ≥75% of patients who experienced them at least some of the time were kidney failure (100%), open sores (95%), blood clots (92%), finger ulcers (91%), migraines (87%), difficulty walking (84%), fainting (84%), stool incontinence (82%), fatigue (81%), swollen joints (80%), joint pain (79%), difficulty washing (79%), RP (78%), difficulty sleeping (78%), muscle pain (77%), side effects of medications (77%), fever (76%), difficulty holding objects (76%), difficulty opening hands (75%), shortness of breath (75%), carpal tunnel syndrome (75%) and liver inflammation (75%).

Discussion

The symptoms with the highest frequency, which were also the most likely to have at least moderate impact on daily activities were fatigue, RP, stiff hands, joint pain and difficulty sleeping. Previous studies have reported that patients with SSc have higher levels of fatigue and pain than the general population, with levels comparable to those of patients with other rheumatic diseases [4–6]. Contractures and deformities of the hand, consisting of decreased flexion and limited extension as well as reduced thumb abduction, are common and contribute substantially to disability in SSc [19]. The only study that has investigated sleep problems in SSc found that 19 (70%) of 27 people had reduced sleep efficiency compared with age-adjusted norms [20]. Patients also reported a number of other problem symptoms at relatively high rates or impact, some of which have not been the subject of focused research.

TABLE 2 Frequency and impact of 69 symptoms (n = 464)

Symptoms	n	Frequency ≥ sometimes		Impact ≥ moderate		Impact ≥ moderate among patients with frequency ≥ sometimes (%)
		Rank	n (%)	Rank	n (%)	
Fatigue	463	1	412 (89)	1	334 (72)	81
RP	462	2	397 (86)	2	310 (67)	78
Stiffness of hands	462	3	375 (81)	5	274 (59)	73
Joint pain	464	4	375 (81)	3	299 (64)	79
Difficulty sleeping	464	5	351 (76)	4	275 (59)	78
Skin tightening	463	6	333 (72)	7	247 (53)	74
Muscle pain	463	7	327 (71)	6	253 (55)	77
Tender joints	464	8	327 (71)	8	238 (51)	72
Itching	463	9	318 (69)	31	126 (27)	39
Erectile dysfunction	54	10	37 (69)	10	27 (50)	73
Difficulty making fist	464	11	312 (67)	11	228 (49)	73
Difficulty holding objects	462	12	309 (67)	9	236 (51)	76
Dry mouth	464	13	305 (66)	27	146 (32)	47
Heartburn	461	14	304 (66)	16	196 (42)	64
Skin colour change	462	15	296 (64)	42	109 (24)	36
Shortness of breath	463	16	292 (63)	13	221 (48)	75
Difficulty climbing stairs	463	17	291 (63)	15	214 (46)	73
Difficulty concentrating	463	18	286 (62)	18	182 (39)	63
Difficulty remembering	463	19	284 (61)	21	167 (36)	58
Dilated hand vessels	459	20	283 (61)	17	188 (41)	66
Swollen joints	464	21	282 (61)	12	226 (49)	80
Difficulty swallowing	461	22	268 (58)	23	160 (35)	59
Dry eyes	463	23	268 (58)	28	141 (30)	52
Difficulty walking	463	24	254 (55)	14	214 (46)	84
Skin pain	464	25	248 (53)	19	176 (38)	71
Vaginal dryness	407	26	215 (52)	29	120 (29)	56
Numbness	462	27	241 (52)	26	146 (32)	60
Difficulty in/out car	463	28	239 (52)	24	160 (35)	67
Diarrhoea	463	29	233 (50)	20	168 (36)	72
Constipation	463	30	230 (50)	35	121 (26)	52
Difficulty opening hand	464	31	219 (47)	22	165 (36)	75
Bad taste in mouth	461	32	201 (43)	54	76 (16)	37
Difficulty faucet	462	33	200 (43)	33	125 (27)	62
Calcium deposits	464	34	194 (42)	34	123 (27)	63
Burning eyes	464	35	192 (41)	43	107 (23)	55
Hypersensitivity	464	36	188 (41)	46	95 (21)	50
Persistent coughing	463	37	187 (40)	38	113 (24)	60
Difficulty dressing	463	38	185 (40)	30	132 (28)	71
Dilated face vessels	461	39	184 (40)	59	58 (13)	31
Gritty eyes	463	40	182 (39)	47	94 (20)	51
Choking	461	41	181 (39)	45	98 (21)	54
Difficulty chewing	461	42	179 (39)	37	113 (24)	63
Skin rashes	463	43	169 (36)	51	84 (18)	49
Nausea	463	44	167 (36)	41	111 (24)	66
Finger ulcers	464	45	166 (36)	25	151 (33)	91
Side effects	461	46	156 (34)	36	121 (26)	77
Chest pain	463	47	158 (34)	55	76 (16)	48
Dental caries	462	48	155 (33)	50	85 (18)	54
Rapid heart rate	463	49	152 (33)	52	80 (17)	52
Difficulty opening mouth	462	50	150 (32)	48	89 (19)	59
Food stuck	463	51	145 (31)	56	74 (16)	51
Difficulty washing	462	52	139 (30)	39	111 (24)	79
Stool incontinence	459	53	135 (29)	40	111 (24)	82
Painful swallowing	461	54	132 (28)	49	88 (19)	67
Open sores	464	55	132 (28)	32	126 (27)	95
Irregular heart rate	462	56	115 (25)	58	64 (14)	55
Migraines	463	57	115 (25)	44	101 (22)	87
Carpal tunnel	463	58	103 (22)	53	78 (17)	75
Weight loss	463	59	96 (21)	60	58 (13)	60

(continued)

TABLE 2 Continued

Symptoms	n	Frequency ≥ sometimes		Impact ≥ moderate		Impact ≥ moderate among patients with frequency ≥ sometimes (%)
		Rank	n (%)	Rank	n (%)	
Mouth ulcers	464	60	86 (19)	62	49 (11)	57
Brushing teeth	461	61	84 (18)	61	57 (12)	67
Fainting	464	62	78 (17)	57	66 (14)	84
Thyroid problems	463	63	68 (15)	64	27 (6)	39
Gland swelling	462	64	65 (14)	65	21 (5)	32
Fever	464	65	55 (12)	63	42 (9)	76
Nose ulcers	461	66	42 (9)	66	18 (4)	42
Liver inflammation	462	67	16 (3)	69	12 (3)	75
Blood clots	464	68	14 (3)	68	13 (3)	92
Kidney failure	461	69	13 (3)	67	13 (3)	100

There are limitations that should be considered in interpreting the results of this study. Primarily, the study used a convenience sample of survey respondents and relied upon self-report of a diagnosis of SSc by a health care provider, the reliability of which is not known. Recruitment methods included physicians involved in the Canadian Scleroderma Research Group, support groups and patient advocacy groups, which may have influenced the representativeness of the sample. In addition, a large portion of the survey dissemination and response was electronic (newsletters, web sites and the online survey itself), which may have influenced the characteristics of respondents. On the other hand, whereas all of the patients in the Canadian Scleroderma Research Group Registry and most other academic cohorts are seen by a rheumatologist, only 63% of survey respondents listed a rheumatologist as the health care professional who primarily cared for their disease, which may be more representative of patients with SSc. Approximately half of the patients did not know their SSc subtype, likely because physicians often do not use this terminology with patients. Therefore, we were unable to explore possible differences between limited and diffuse SSc. Patients tended to have long disease duration and, of patients who reported a diagnosis, most had limited SSc. Patients with early stage disease or diffuse SSc may have different problems. Other limitations of this study include the single-item assessment of symptoms, the lack of precise medical information due to the self-report nature of the survey and the non-inclusion of mental health problems in the symptom list.

In summary, this is the first study to assess the frequency and impact of such a broad range of problems experienced by a large number of people living with SSc. A strength of this study is that the protocol was developed collaboratively by patients and researchers with extensive experience in SSc. Collaborative, multi-centre, multi-disciplinary efforts that involve patients and patient advocates are crucial to better understand the nature of problems that impact QoL in SSc and to develop successful interventions to improve QoL and well-being for people living with SSc.

Rheumatology key messages

- Knowledge about the range of problems experienced by patients with SSc is limited.
- Common, high-impact problems include fatigue, RP, hand problems, joint pain and difficulty sleeping.
- Research on care for important, understudied problems, including fatigue, hand and sleep problems is needed.

Acknowledgements

The authors extend their gratitude to all the patients who completed the survey, the survey committee, Sclérodermie Québec, the Scleroderma Society of Canada, provincial organizations and chapters who distributed the survey, as well as Canadian Scleroderma Research Group recruiting rheumatologists and their research teams for promoting the survey. We would also like to thank members of the Scleroderma Society of Canada and provincial chapters who participated in the development of the survey and/or attended the Canadian Institute of Health Research funded Joint Patient Researcher Meeting to Interpret and Plan for Dissemination of Scleroderma Patient Survey Results, Robert M Buzza (British Columbia), Mary Beth Clark (Nova Scotia), Grant Dustin (Alberta), Shirley Haslam (Ontario), Marion Pacy (Manitoba) and Maureen Worrion-Sauve (Ontario). Dr Thombs and Dr Hudson were supported by New Investigator Awards from the Canadian Institutes of Health Research and Établissement de Jeunes Chercheurs awards from the Fonds de la Recherche en Santé du Québec. Ms. Schieir was supported by a Fonds de la Recherche en Santé du Québec Bourses de Formation – Formation Maîtrise. Dr Baron is the director and Dr Taillefer is the National coordinator of the Canadian Scleroderma Research Group, which receives grant funding from the Canadian Institutes of Health Research, the Cure Scleroderma Foundation, the Scleroderma Society of Canada and its provincial

Chapters, the Scleroderma Society of Ontario, Sclérodémie Québec, Actelion Pharmaceuticals and Pfizer Pharmaceuticals.

Funding: This project was partially funded by a Meetings, Planning and Dissemination grant from the Canadian Institutes of Health Research awarded to Dr Thombs.

Disclosure statement: The authors have declared no conflicts of interest.

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