Measurement of fatigue and discomfort in primary Sjögren’s syndrome using a new questionnaire tool

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Objective. Fatigue is a prominent symptom in primary Sjögren’s syndrome (PSS). We set out to compare existing instruments and a new tool for measuring fatigue and general discomfort in PSS, with systemic lupus erythematosus (SLE), rheumatoid arthritis (RA) and healthy controls.

Methods. Groups of female Caucasian PSS patients completed a new questionnaire developed from PSS patients’ own vocabulary, as well as the SF-36, WHOQOL-BREF and HAD scales. For comparison, the questionnaire was also completed by groups of SLE and RA patients and healthy controls.

Results. Each disease group differed significantly from healthy controls on each facet of fatigue and general discomfort in the new tool. Somatic fatigue was worst in RA, while mental fatigue was worst in PSS and SLE. The facets of somatic fatigue and discomfort in the new tool correlated well with comparable domains in existing scales.

Conclusions. Fatigue in PSS can be measured using this new Sjögren’s-based psychometric instrument. The new questionnaire tool was more sensitive than the SF-36, WHOQOL-BREF and HAD at distinguishing the three rheumatic disorders from controls.

Key words: Primary Sjögren’s syndrome, Questionnaire tools, Fatigue and discomfort.

Primary Sjögren’s syndrome (PSS) is a multisystem immunemediated disease characterized by chronic inflammation of the exocrine glands (especially the salivary and lacrimal glands) [1] that become dysfunctional, leading to clinical symptoms of dry eyes and dry mouth. PSS is found in patients of both sexes at all ages but mainly affects women during the fourth and fifth decades of life, with a female: male ratio of 9:1. Sjögren’s syndrome can also occur in association with other autoimmune diseases such as rheumatoid arthritis (RA), systemic lupus erythematosus (SLE) or scleroderma [secondary Sjögren’s syndrome (SS)].

The spectrum of PSS extends from an organ-specific disorder (autoimmune exocrinopathy) to a systemic process that may also involve the musculoskeletal, pulmonary, gastrointestinal, hepatobiliary, haematological, vascular, dermatological, renal or nervous systems [2].

Substantially reduced health-related quality of life has been demonstrated in patients with PSS, using the 36-item form of the Medical Outcomes Study Short-Form 36 (SF-36) questionnaire [3, 4]. These and other studies [5] have shown that disabling fatigue is a prominent symptom for many patients [6] and is also regarded as an important symptom by specialists looking after patients with this condition [7]. In order to develop therapies for fatigue in PSS, however, it is necessary to be able to characterize it and measure its severity.

The assessment of fatigue can be confined to answering a single question, e.g. rating ‘how fatigued are you?’ [8, 9]. However, a number of multi-item questionnaires of fatigue have been developed for studying patients with chronic fatigue or cancer [10–14]. The more detailed information that they generate may reveal more about the nature of the fatigue in these disorders and be more useful in measuring outcomes in clinical studies. The responses have been interpreted as measuring either ‘fatigue’ as a whole [11, 13] or as several different components, or subscales, of fatigue such as in the 20-item multidimensional fatigue inventory (MFI) [14]. Patients with PSS have more severe symptoms of fatigue than controls on all five subscales of the MFI: general fatigue, physical fatigue, reduced activity, mental fatigue and reduced motivation—although only the former three when depression was factored out [5]. The 10-item scale of Chalder et al. [13] has also identified substantial fatigue in PSS [15]. How the fatigue in PSS compares with that in other rheumatic disorders such as RA or SLE is less well described. Barendregt et al. [5] using the MFI, for example, did not identify any differences in subscale scores between PSS and RA patients.
In order to establish an assessment tool that is fully effective in characterizing the pattern of fatigue associated with PSS and how it compares with fatigue in other disorders, it is best to start from patients’ own descriptions of their symptoms [12]. Therefore the new measure of fatigue and general discomfort used in the present study was developed solely from words in which patients with PSS expressed their complaints of fatigue, discomfort and pain. Psychometric construct analysis of ratings of severity of these symptoms established six facets of fatigue (partly related to the MFI’s five scales) and two generalized aspects of discomfort in PSS, with a similar verbal structure in SLE and to a great extent in RA.

We now report the use of this new tool in measuring the severity of fatigue and general discomfort in PSS in comparison with existing questionnaires [the SF-36, the Hospital Anxiety and Depression Scale (HAD)] [16] and the World Health Organization’s multicultural quality of life instrument in its brief form (WHOQOL-BREF) [17] and how the pattern of fatigue measured by this tool in PSS compares with those observed in other rheumatic disorders (SLE and RA).

Patients and methods

Patients

Multi-centre research ethics committee (MREC) approval was obtained prior to starting this study. Since Sjögren’s syndrome is predominantly a condition affecting females and because of the very small number of non-Caucasians in our cohort of patients, it was decided to limit the study to female Caucasian patients. In a preliminary evaluation of our PSS cohort, almost all of the patients were between 35 and 74 years old, and this age range was therefore used in the recruitment of the control groups.

Volunteers with PSS (n = 18), RA (n = 18) and SLE (n = 11) were recruited from Birmingham, UK rheumatology clinics between April 1999 and January 2000 to complete a pilot version of a questionnaire of symptoms of fatigue and generalized discomfort, using vocabulary based on 3-day diaries and focus group interviews of 12 patients with PSS together with a checklist of a broad range of localized symptoms. Extrapolating previous data from PSS patients using the SF-36 (data not shown) which showed that n = 50 will detect differences of 20% of a standard deviation between groups at 80% power with a 95% CI ($P < 0.05$), we aimed to recruit at least 60–100 patients per group in the main study to allow for some margin of error. This sample size was achieved for all groups (as set out in the following paragraphs) although the number of patients with PSS recruited was greater than this.

One hundred and thirty seven consecutive female Caucasian patients with PSS were recruited from 12 participating centres in the UK. Patients fulfilled the EU-USA Consensus Criteria [18] which require the presence of either anti-Ro/La antibodies and/or a positive labial gland biopsy (focus score $\geq 1$).

Ninety four consecutive RA patients fulfilling the 1987 revised ARA criteria for the classification of RA [19] were recruited from a general rheumatology clinic in Birmingham, UK. Patients with possible or definite secondary SS according to the preliminary EC criteria [20] were excluded.

A specialist clinic at the University of Birmingham, UK, contributed 92 consecutive patients with SLE fulfilling the 1982 revised criteria for the classification of SLE [21]. Again, patients with possible or definite secondary SS were excluded.

The community control group included 103 healthy women without significant medical conditions, who did not suffer from oral or ocular dryness (e.g. due to beta-blockers, antidepressants, antihistamines, diuretics or other drugs that cause oral/ocular dryness). They were recruited by postal invitation from the lists of two general practitioners in the Birmingham area.

The original diagnostic category was checked during the study by reported oral and ocular symptoms and Schirmer’s I-test, unstimulated salivary flow and anti-Ro/La antibodies (ELISA, Binding Site, Birmingham, UK). RA disease activity scores were recorded for the RA group and BILAG scores of SLE disease activity for the SLE group.

Fifteen participants did not meet the appropriate classification criteria and were excluded. After further excluding 46 patients with secondary SS, the remaining 380 participants with confirmed diagnoses comprised 137 patients with PSS, 66 with SLE, 74 with RA and 103 community controls. A small number of recruits were found to be outside the originally specified age range but it was decided to include them in the study; seven PSS, eight SLE, two RA and four controls were under 35 years; five of the RA group were over 75 years.

The number of individuals per group size (%) fulfilling the standard criteria for fibromyalgia [22] were: PSS 6/137 (4.4%), SLE 3/66 (4.5%), RA 1/74 (1.4%), and none of the healthy controls. Although all these percentages are small, they varied significantly among the groups ($x^2 P < 0.05$), being greater in the PSS and SLE groups than in the RA and controls.

Methods

PSS patients identified 28 phrases for fatigue and pain or discomfort during focus group discussion of their 3-day diaries. These phrases were used to construct an initial version of a symptoms questionnaire of fatigue and general discomfort. The responses from a pilot group of PSS, RA and SLE patients (see above) generated five clusters of near-synonymous phrases which we hypothesized to be distinct facets of fatigue (four somatic and one mental).

In the main study reported here, the mental fatigue cluster was split into two potentially distinct facets of poor concentration and poor memory, giving six hypothesized facets of fatigue (four somatic and two mental). The same process identified, in addition, two apparently distinct facets of general discomfort. These eight facets included 19 individual symptom phrases (Table 1). The data

### Table 1. Domains and facets in the Sjögren’s-based questionnaire on fatigue and generalized discomfort

<table>
<thead>
<tr>
<th>Domain</th>
<th>Facet</th>
<th>Phrases in items within the facet</th>
<th>Nearest MFI scale [14]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Somatic fatigue</td>
<td>Need rest</td>
<td>Feeling a need to rest, feeling tired, feeling exhausted, needing to sleep</td>
<td>General fatigue</td>
</tr>
<tr>
<td></td>
<td>Poor starting</td>
<td>It being hard to get going, things take an effort, feeling ‘it’s a battle’</td>
<td>Reduced motivation</td>
</tr>
<tr>
<td></td>
<td>Low stamina</td>
<td>Feeling it’s hard to keep going, feeling easily worn out, lack of energy</td>
<td>Reduced activity</td>
</tr>
<tr>
<td></td>
<td>Weak muscles</td>
<td>Lack strength in your muscles, feeling weak</td>
<td>Physical fatigue</td>
</tr>
<tr>
<td>Mental fatigue</td>
<td>Poor concentration</td>
<td>Not thinking clearly, feeling it’s hard to concentrate</td>
<td>Mental fatigue</td>
</tr>
<tr>
<td></td>
<td>Poor memory</td>
<td>Forgetting things, making mistakes</td>
<td></td>
</tr>
<tr>
<td>General discomfort</td>
<td>Discomfort/pains, all-over ache</td>
<td>Pains, discomfort (locale unstated), aching all over</td>
<td></td>
</tr>
</tbody>
</table>

The questionnaire can be viewed as supplementary data at *Rheumatology Online.*
reported here are scores on facet questions that group the phrases indicated in Table 1. We are currently preparing for publication a detailed paper on the confirmatory analysis of the facet structure and these scores correlate well with factor scores from scoring of single-phrase items.

The resulting instrument for measuring symptoms of fatigue and generalized discomfort was self-administered to assess the severity of symptoms by rating each symptom term and facet group (Table 1) for how the respondent had felt at worst in the last 2 weeks, from a score of 0 for ‘no problem at all’ to a score of 7 for ‘as bad as imaginable’. The scores reported here for each facet were generated by including all the phrases for a given facet within one question. Patients completed the symptoms questionnaire either prior to attending or during clinic appointments.

Other questionnaire instruments

A number of previously validated instruments were also simultaneously administered to the four groups.

The SF-36 [23] is a widely used questionnaire designed to evaluate health-related quality of life in individuals with medical disorders. The 36 question items have been split among eight domains, named general health (GH), physical functioning (PF), role-functioning physical (RP), bodily pain (BP), social functioning (SF), role-functioning emotional (RE), mental health (MH) and vitality (VT).

The HAD is a 14-item self-assessment questionnaire used to screen for clinically significant depression and anxiety in individuals with physical illness [16].

The WHOQOL-BREF [17] asks respondents to rate their overall ‘quality of life’ and ‘satisfaction with health’ and 24 further items from four domains: physical (PHY), psychological (PSY), social relationships (SOC) and environment (ENV). Participants were asked to assess various aspects of their life at present and to circle the number that best represented how they felt. The WHOQOL-BREF contains questions of two types: one ‘positive’ where a plus score means good quality or satisfied, a negative score means poor quality or dissatisfied, and a zero score is neither; and the other ‘negative’ where a zero rating indicates poor quality of life and a high rating a good quality of life. Domain scores were calculated and transformed to a 0 to 100 scale according to the published algorithm [17]. Higher domain scores denote a better quality of life.

Data analysis

All analyses were conducted in SPSS for Windows (version 6.1.3). The incidence of missing entries was low, with 0.6% of possible responses omitted in the Sjögren’s-based symptoms questionnaire. After applying published algorithms to correct for missing entries [17, 23], the number of remaining cases comprised 13 (3.4%) for SF-36 scores, 14 (3.7%) for HAD anxiety scores, 8 (2.1%) for HAD depression and 12 (3.2%) for WHOQOL-BREF domain scores. Formal scoring checks were carried out to confirm the accuracy of the SF-36, HAD and WHOQOL-BREF domain scores.

Analysis of variance (ANOVA) was used to test that each measure discriminated between the control and diagnostic groups and to identify differences between diagnostic groups. Pearson’s correlation coefficient derived from the χ² test (corrected for continuity) assessed the degree of association between caseness in HAD, SF-36 and WHOQOL-BREF. Cases of poorer quality of life from HAD, SF-36 and WHOQOL-BREF were categorized as below the 25th centile score for each item or scale within each diagnostic group, while those above the 75th centile were classified as having the least severe of ‘worst’ experiences. As an estimate of the statistical significance of the r value, for n = 137 (number of PSS patients in the study), an r value above 0.23 has a P value of less than 0.01 and r > 0.31 has a P value of <0.001. With respect to

Severity of symptom

![Severity of symptom graph](image)

Fig. 1. Mean and 95% confidence intervals for fatigue and general discomfort ratings at worst in the Sjögren’s based questionnaire tool (7 = worst imaginable) for healthy controls and three disease groups.
the strength of the relationship, \( r = 0.5 \) is 25% of the covariance while \( r = 0.8 \) is 64%.

On the basis of integer scores closest to the mid-point between the upper 95% confidence interval (CI) for healthy controls and the lower CI for the disease group (Fig. 1) scoring worst severity to be above 2 for a facet of the profiles of fatigue and discomfort was categorized as a case, with the exception of Need Rest and General Discomfort, where a score of 3 or more was used. For the subscales of somatic and mental fatigue and general discomfort, a case was taken to be in two or more facets in the four-facet domain of Somatic Fatigue and one or two facets in the two-facet domains of Mental Fatigue and General Discomfort.

Definite or possible cases of anxiety or depression were categorized by the HAD [16] as scoring above 8 or more. No caseness cut-offs were available from the norms for the SF-36 and WHOQOL-BREF and so discriminant analysis was used to determine sensitivity and specificity from these scores.

The sensitivity of a measure for PSS was the percentage of PSS cases correctly classified into the PSS group. Specificity was the percentage of true negatives among the community control group.

**Results**

**Characteristics of patients**

The characteristics of the patient and comparison groups are set out in Table 2. The SLE group was significantly younger [mean 47 yr (s.d. 11 yr)] than the PSS, RA and healthy controls groups [means 57–60 yr (s.d. 10–12 yr); \( P < 0.001 \)]. This will be addressed below. The PSS group had a shorter disease duration from diagnosis [mean 5 yr (s.d. 5yr)] than the SLE [11 (9)] or RA [12 (11)] groups (\( P < 0.001 \)). Since symptom onset in PSS often pre-dates the formal diagnosis by several years, this may not be biologically significant and will not be addressed further.

**Fatigue and discomfort in rheumatic diseases and health**

Each of the four facets of somatic fatigue in the questionnaire of fatigue and generalized discomfort was rated as significantly more severe at its worst over the previous 2 weeks by each of the three disease groups (mean scores 2.7–4.4) than by healthy controls from the community (mean scores 1.4–2.2) (Fig. 1) (\( P \) values < 0.001). Patients with RA on average rated each facet of somatic fatigue as more severe than PSS or SLE participants did, consistently so for Physical domain of WHOQOL-BREF in PSS (\( r = 0.62 \) to –0.69). Weak Muscles and Low Stamina facets were validated in PSS by physical item ‘energy for everyday activities’, and Weak Muscles and Low Stamina facets were validated in PSS by negative correlations (both –0.60) with the WHOQOL-BREF Physical item ‘energy for everyday activities’, and Weak Muscles with WHOQOL-BREF ‘able to do daily activities’ (–0.62).

**Quality of life in PSS**

Group mean scores on most scales in the SF-36 and WHOQOL-BREF were almost as high in PSS as in RA, and higher than in SLE (Fig. 2). Few of these differences between syndromes were statistically significant, but each of the three groups differed from healthy controls, each having \( P < 0.008 \). Patients with PSS clearly have seriously impaired quality of life, comparable to that of patients with RA or SLE (Fig. 2).

**Associations with other instruments in PSS**

**Somatic fatigue.** The severity of each facet of somatic fatigue correlated negatively with the score for the Vitality scale of the SF-36 (\( r = -0.53 \) to –0.70). The SF-36 Vitality item ‘felt tired’ was most highly correlated with the fatigue and discomfort questionnaire Need Rest facet (which included the word ‘tired’) and Vitality ‘full of life’ related to the motivational facets of the fatigue and discomfort questionnaire, Poor Starting and Low Stamina. The Vitality item ‘lot of energy’ also related to Low Stamina.

As predicted, the four facets of somatic fatigue related to the Physical domain of WHOQOL-BREF in PSS (\( r = -0.62 \) to –0.69). Weak Muscles and Low Stamina facets were validated in PSS by negative correlations (both –0.60) with the WHOQOL-BREF Physical item ‘energy for everyday activities’, and Weak Muscles with WHOQOL-BREF ‘able to do daily activities’ (–0.62).

### Table 2. Characteristics of the groups of patients and healthy controls

<table>
<thead>
<tr>
<th>Feature</th>
<th>PSS patients (n = 137)</th>
<th>SLE patients (n = 66)</th>
<th>RA patients (n = 74)</th>
<th>Controls (n = 103)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years [mean (s.d.)]</td>
<td>59.0 (11.7)</td>
<td>46.8 (11.2)*</td>
<td>60.3 (10.3)</td>
<td>57.0 (12.3)</td>
</tr>
<tr>
<td>Disease duration in years [mean (s.d.)]</td>
<td>5.4 (5.0)*</td>
<td>10.7 (8.8)</td>
<td>12.3 (11.1)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Anti-Ro/La antibodies present</td>
<td>110/137 (80%)</td>
<td>29/66 (44%)</td>
<td>2/71 tested (3%)</td>
<td>2/102 tested (2%)</td>
</tr>
<tr>
<td>Labial gland biopsy</td>
<td>75/80 tested positive, 5/80 non-diagnostic</td>
<td>Not performed</td>
<td>Not performed</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Disease modifying therapy and/or prednisolone</td>
<td>38/137 (28%)</td>
<td>50/66 (76%)</td>
<td>67/74 (91%)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Disease activity score (DAS)</td>
<td>Not available</td>
<td>Nos of worst BILAG domain score: A = 1, B = 18, C = 41, D = 6, E = 0</td>
<td>Mean ± s.d. DAS score = 4.3 ± 1.3</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

*Differs from the other groups at \( P < 0.001 \). Groups were not compared statistically on the other four parameters.
However, these convergences were not independent of those with the SF-36, because WHOQOL-BREF Physical was well correlated with SF-36 Vitality ($r = 0.74$) as well as all the other SF-36 scales ($r = 0.70$ to $0.82$) except Mental Health and Role Emotional.

The Need Rest, Poor Starting and Low Stamina somatic fatigue facet scores did not relate clearly to the HAD scales in PSS (Depression $r = 0.49$–0.52; Anxiety $r = 0.36$–0.45).

**Mental fatigue.** Neither of the two facets of the mental fatigue domain was substantially related to SF-36 Mental Health (MH) ($r = -0.27$ to $-0.44$), the WHOQOL-BREF Psychological Domain ($r = -0.32$ to $-0.47$) or the HAD Anxiety/Depression scale scores ($r = -0.34$ to $-0.48$).

**Discomfort.** Severity ratings in the facet of total Discomfort/pains were well correlated with SF-36 Bodily Pain (BP) scale scores ($r = 0.65$) and also with the BP item ‘how much pain’ ($r = 0.67$). In PSS, the phrase ‘pain interferes with work’ ($r = -0.56$) and the facet consisting of the one phrase ‘aching all over’ correlated modestly with BP ‘pain interferes with work’ ($r = -0.53$). Nevertheless, General Discomfort did not relate to SF-36 Vitality, providing some convergent validity in this syndrome to the distinction between pain and fatigue.

The Discomfort/pains facet correlated substantially also with the Physical domain of WHOQOL-BREF ($r = 0.62$), but this effect was not attributable to any particular items in the PHY scale. As expected, the facets of General Discomfort did not relate substantially to HAD scores.

### Sensitivity and specificity

The four facets within the Somatic Fatigue domain had sensitivities for PSS of 77–88% and specificities of 60–71% (Table 3). The sensitivity and specificity data for the two facets within the Mental Fatigue domain were 67–70% and 70–73% respectively and for the two facets within the General Fatigue domain were 65–85% and 55–77% respectively (Table 3).

Sensitivity and specificity data for the other questionnaires are also presented in Table 3. Although the data for the
Sjögren’s-based questionnaire have yet to be fully validated in a further independent cohort, the data presented here at least suggest broad comparability with the other instruments with the potential for superiority if these results are reproduced in future studies.

Discussion

A number of studies have used existing instruments to show that fatigue is a prominent and disabling feature of PSS [3–5, 15, 24, 25]. It is not known, however, whether these tools will be able to detect improvement in patients with PSS in response to therapeutic intervention or provide a better understanding of the pattern of the fatigue compared with other disorders. Since the most logical starting point for such a questionnaire instrument is with patients’ own vocabulary, we have constructed a Sjögren’s-based fatigue and discomfort questionnaire (Booth DA et al., in preparation). We now report on the use of this new tool in measuring the severity of fatigue and general discomfort in PSS in comparison to existing questionnaires and other rheumatic disorders.

Our initial studies had established four facets of physical (somatic) fatigue and two aspects of mental fatigue, further advancing the multifactorial approach of Smets et al. [14]. Two distinct ‘motivational’ facets of somatic fatigue were identified—not only the difficulty of starting activities identified by Smets et al. [14] as Reduced Motivation, e.g. in RA, but also difficulty in keeping activities going, which was severe in PSS and is possibly more related to the MFI subscale of Reduced Activity.

In PSS, discomfort was also separated into ‘aching all over’ and a total or average of localized ‘pains or discomfort’. These findings do not deal with the temporal aspects of discomfort as detailed in the McGill Pain Questionnaire, but these did not appear to be important to patients in their freely written diaries.

The eight-facet structure of somatic and mental fatigue and general discomfort was also seen in SLE and RA patients but with differing profiles of severity, and also in a community control group, although at much lower levels of symptom intensity. Of particular note was the similarity in the profile of responses of the PSS and SLE groups (Fig. 1) while the RA group scored higher across the domains of ‘physical’ fatigue and discomfort. Such results indicate that fatigue may arise from a diversity of physiological bases that occur in both disease and health but are aggravated to various degrees in different diseases. The new scales provide, therefore, a tool to study such hypotheses of fatigue mechanisms (e.g. of the effects of cognitive dysfunction or end-organ damage) in conditions such as PSS, which involve fatigue as an important disease symptom.

This study also confirmed previous findings that patients with PSS, SLE and RA have reduced health-related quality of life as measured by the MOS SF-36 questionnaire—in this study across all eight of its domains. The PSS and SLE groups showed a very similar pattern of responses across all eight domains, while the RA group scored lower than the PSS and SLE groups in five domains, particularly those with a more ‘physical’ component. These observations were also supported by data derived from using the recently developed quality of life instrument WHOQOL-BREF. Its use has not previously been reported in PSS.

The results of this study, however, did not support the hypothesis that the fatigue associated with PSS can largely be accounted for by increased levels of depression or fibromyalgia, as previously proposed [26, 27]. We have not examined, however, the effects of other potential confounding factors in this study such as other co-morbidities or occupational status.

The sensitivity data indicate that the Sjögren’s-based questionnaire tool can be used to check if the severity of fatigue is pathological in the three rheumatic diseases studied and is equivalent in range to the SF-36 in the measurement of patient status. One potential caveat is that the sensitivity and specificity of the questionnaire need to be re-evaluated in an independent cohort of patients in order to confirm that the cut-off values chosen perform satisfactorily in correctly classifying individuals.

The questionnaire described in this paper, together with our recently published Sicca Symptoms Inventory [28] provide a suite of tools to assess the key symptoms of Sjögren’s syndrome patients. Further work is required, however, to evaluate their usefulness in measuring change in symptom severity during clinical therapeutic trials in PSS.

The authors have declared no conflicts of interest.

Supplementary data

Supplementary data are available at Rheumatology Online.

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References