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Original article

The Psoriatic Arthritis Registry of Turkey: results of a multicentre registry on 1081 patients

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Abstract

Objective. The aim was to assess the characteristics of PsA, find out how well the disease is controlled in real life, demonstrate the treatments and identify the unmet needs.

Methods. The PsA registry of Turkey is a multicentre Web-based registry established in 2014 and including 32 rheumatology centres. Detailed data regarding demographics for skin and joint disease, disease activity assessments and treatment choices were collected.

Results. One thousand and eighty-one patients (64.7% women) with a mean (S.D.) PsA duration of 5.8 (6.7) years were enrolled. The most frequent type of PsA was polyarticular [437 (40.5%)], followed by oligoarticular [407 (37.7%)] and axial disease [372 (34.4%)]. The mean (S.D.) swollen and tender joint counts were 1.7 (3) and 3.6 (4.8), respectively. Of these patients, 38.6% were on conventional synthetic DMARD monotherapy, 7.1% were on anti-TNF monotherapy, and 22.5% were using anti-TNF plus conventional synthetic DMARD combinations. According to DAS28, 86 (12.4%) patients had high and 105 (15.2%) had moderate disease activity. Low disease activity was achieved in 317 (45.7%) patients, and 185 (26.7%) were in remission. Minimal disease activity data could be calculated in 247 patients, 105 of whom (42.5%) had minimal disease activity. The major differences among sexes were that women were older and had less frequent axial disease, more fatigue, higher HAQ scores and less remission.

Conclusion. The PsA registry of Turkey had similarities with previously published registries, supporting its external validity. The finding that women had more fatigue and worse functioning as well as the high percentage of active disease state highlight the unmet need in treatment of PsA.

Key words: psoriatic arthritis, registry, disease activity

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Rheumatology key messages

- Almost half of PsA patients have active disease.
- The high prevalence of active disease in PsA shows the unmet need for treatment in real life.
- Women with PsA have higher disease activity, more function loss and fatigue compared with men.

Introduction

PsA is a heterogeneous disease including different subtypes of joint manifestations [1]. The extension of inflammation beyond the joints is another interesting feature of PsA [2]. Musculoskeletal manifestations appear to be more complex than those in other types of inflammatory arthritis, such as dactylitis, which is a frequent finding involving tendons, entheses, subcutaneous tissue, multiple joints and, possibly, the nails. In addition, anatomically anchored structures, such as the entheses, the nails and the joints, seem to be involved in the same process [3]. To date, it has not been clarified which factors lead to which subtype of joint disease other than women having more frequent peripheral arthritis, men with more spinal disease with a more severe disease course associated, and HLA-B27 being associated with more severe axial inflammation [4–7].

Genetic and environmental factors may play a role in the prevalence of PsA, and the disease features may not be uniform across cultures. Therefore, epidemiological data from different genetic backgrounds are needed for a better understanding of the disease.

To be able to understand the nature of PsA in our population, a multicentre registry was built in Turkey in 2014. The objective of this registry was to see the characteristics of PsA, find out how well the disease is controlled in real life, demonstrate the treatments and identify the unmet needs. To make sure that the registry represents the whole country, a multicentre study was conducted. Here, the demographics of our registry are given in comparison with the other well-established registries.

Methods

General information

The psoriatic arthritis registry of Turkey (PsART) was established in 2014 and includes 32 rheumatology centres across Turkey. PsART data are collected using a Web-based system (www.favor.org). Individual centres have direct access to their own local data, whereas the principal investigators (U.K. and S.Z.A.) have access to the centralized data set. Data are collected following the recommendations of a survey led by the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis at the annual meeting in 2007 [8]. Ethical approval was obtained from the Hacettepe University Ethics Board, and all patients gave informed consent prior to data collection. The data that are presented in this article represent one of the main outcomes of the PsART registry.

Collection of demographic data

Sex, date of birth, education level, smoking status, weight, height and calculated BMI were collected.

Data for psoriasis

Psoriasis onset date (month/year), type of psoriasis (plaque, pustular, inverse, erythrodermic), initial skin involvement site, family history of psoriasis and PsA were collected. Nail involvement was recorded as presence or absence as well as the type of nail involvement (pitting and/or onycholysis).

Data for PsA

Consecutive subjects with a diagnosis of PsA according to the rheumatologists were recruited to the registry. Fulfilling the ClASsification criteria for Psoriatic Arthritis (CASPAR) criteria was not mandatory but this was also analysed [9]. The data regarding joint involvement included the date of initial diagnosis and the PsA pattern. The presence of axial involvement was based on the physician's assessment, according to the presence of inflammatory lower back pain. In the absence of a validated definition of inflammatory lower back pain in PsA, all items of the Calin *et al.* [10], Assessment of SpondyloArthritis international Society [11] and Berlin Criteria [12] for inflammatory lower back pain were included.

Outcome measures for PsA

Patient-reported outcomes

Patient global assessment (GA), fatigue and pain were assessed with a visual analog scale (VAS) from 0 to 100 mm. The duration of morning stiffness was assessed in minutes. Function and disability were assessed with HAQ [13]. BASDAI [14] and BASFI [15] were used to assess disease activity and function. Skin involvement was assessed by the psoriasis symptom inventory (PSI). The PSI is a relatively new patient-reported outcome measure consisting of eight items assessing skin symptoms and response options on a five-point Likert-type rating scale and includes itching, redness, scaling, burning, stinging, cracking, flaking and pain [16]. The PSI was not included in the registry from the beginning and was added subsequently. For that reason, the PSI data were available for only a subgroup of patients.

Physician-reported outcomes

Physician GA of disease activity (VAS 0–100 mm), swollen (66 joint) joint count and tender (68 joint) joint count were assessed. The joints with damage were recorded

according to clinicians' physical examination and classified according to the presence of ankylosis, subluxation and limitations in the range of motion, telescopic finger and arthritis mutilans. Presence (current or ever) or absence of dactylitis and enthesis were also recorded. The Leeds Enthesis Index (LEI) was used to assess for enthesitis at the following three sites, bilaterally: Achilles tendons, humeral lateral epicondyle and medial femoral condyle [17]. The body surface area percentage was used for skin involvement. Of note, the severity of the skin psoriasis assessment was not mandatory and was therefore recorded only by investigators who were familiar with the scoring.

Laboratory tests

The RF status (positive/negative), ANA and ACPA were collected whenever available.

Treatment protocols

Data on the usage of conventional synthetic DMARDs (csDMARDs; such as MTX, SSZ, HCQ, LEF and CSA), glucocorticoids and anti-TNF agents (adalimumab, etanercept, infliximab and golimumab) were recorded. For each drug, the start dates, initial dosage, withdrawal date, the reason for withdrawal, last dosage as reported by patient report and/or medical records as well as switching were collected.

Dealing with inappropriate and missing data

For cross-sectional analysis, all data were visually screened by three investigators (O.B., U.K. and S.Z.A.), and 450 items that were found inappropriate were sent to the centres with queries. After verification, the numbers (percentages) of missing data were as follows: nail involvement 1 (0.1%), family history 3 (0.3%), PsA joint pattern 8 (0.7%), treatment history 11 (1.0%), smoking 12 (1.1%), fulfilling the CASPAR criteria 16 (1.5%), swollen joint count 38 (3.5%), tender joint count 38 (3.5%), dactylitis 46 (4.3%), inflammatory lower back pain 58 (5.4%), enthesitis 69 (6.4%), LEI 78 (7.2%), morning stiffness 129 (11.9%), educational level 160 (14.8%), initial affected psoriasis area 208 (19.2%), joint count with damage 319 (29.5%), pain VAS 325 (30.1%), fatigue VAS 331 (30.6%), patient GA VAS 348 (32.2%), psoriasis type 371 (34.3%), HAQ 382 (35.3%), physician GA VAS 402 (37.2%), BASDAI 498 (46.1%), BASFI 508 (47.0%), PSI 672 (62.0%), body surface area 675 (62.4%), and PSI or body surface area 456 (42.2%).

Statistical analysis

This was the first cross-sectional analysis at baseline 10 months after launching the PsART. Descriptive statistics were performed with the frequencies and percentages for categorical variables, mean and S.D., or median and range. All data were initially analysed for the whole group, followed by division according to the sex, to determine the differences between women and men. Categorical variables were compared using a χ^2 test. Continuous variables were compared by student's *t* test or Mann-Whitney U test, depending on the distribution of the data. The software used was SPSS 21.0 (Hacettepe University).

Results

General information

Between October 2014 and August 2015, 1081 patients were enrolled in the PsART. Patients were recruited from different regions of Turkey. The CASPAR criteria were fulfilled for 939 (88.2%) patients. Of note, 126 (11.8%) of the patients did not fulfil the CASPAR criteria but were still considered to have PsA according to the physician. Within the whole group, 64.7% were women. Within the inception cohort, for patients who were newly diagnosed, the rate for women was 55.6%. The mean duration of education of the whole group was 8.3 (4.6) years, and 25.5% had a university degree. Current smoking was present in 216 (20.2%) patients, and 387 (36.2%) patients were either current or ex-smokers. Demographic and clinical features are shown in Table 1. The mean PsA duration was 5.8 (6.7) years. The mean duration of psoriasis was 15.2 (11.3) years. Eighty-four of 1081 (7.8%) patients had a new diagnosis of PsA, and 272 (25.3%) patients had the diagnosis for <1 year. Four hundred and twenty-eight (39.6%) had a disease duration of >5 years. Concomitant skin and joint involvement were found in 172 (15.9%) patients, and joint symptoms preceding psoriasis were present in 59 (4.7%) patients. Nail involvement was present in 503 (46.5%) patients.

The most frequent type of PsA was polyarticular [437 (40.5%)], closely followed by oligoarticular [407 (37.7%)] and axial disease [372 (34.4%)]. A minority of patients had only DIP involvement (n = 6, 5.8%) or arthritis mutilans (n = 5, 0.5%). In the current assessment of swollen joints, PIPs (n = 148; 36.4%) were the most commonly affected joints, followed by knees (n = 114; 28.0%), MCPs (n = 94; 23.1%), ankles (n = 92; 22.6%) and wrists (n = 79; 19.4%).

Outcome measures

The mean (S.D.) values for patient- and physician-reported outcome measurements are listed in Table 2. In addition, for the PSI scores, 77 of 409 (18.8%) patients had a score of zero. At least one swollen joint was detected in 507 of 1042 (48.6%) patients, and there were one or more damaged joint in 166 of 762 (21.2%) patients. For LEI, 897 of 1003 (89.4%) patients had zero LEI. An LEI score of 1, 2 and >2 was present in 41 (4.1%), 46 (4.6%) and 19 (1.9%) patients, respectively. The DAS28 (n = 693) data showed that 86 (12.4%) patients had high and 105 (15.2%) had moderate disease activity. Low disease activity was achieved in 317 (45.7%) patients, and 185 (26.7%) of them were in remission. Minimal disease activity (MDA) data could be calculated in 247 patients, 105 of whom (42.5%) had MDA. The percentages of MDA components are shown in Table 3.

Table 1 Demographic, clinic and laboratory features in the psoratic arthritis registry of Turkey

Clinical and laboratory features	All patients (n = 1081)	Female (n = 702)	Male (n = 379)	P-value
Current age, mean (S.D.)	46.9 (12.8)	48.3 (12.8)	44.4 (12.5)	<0.001
Age at PsA, mean (S.D.)	40.9 (13.3)	41.9 (13.7)	38.5 (13.3)	<0.001
Age at PsO, mean (S.D.)	31.7 (14.7)	31.9 (15.4)	29.5 (14.2)	0.015
Current PsO lesion, n (%)	847 (78.6)	540 (77.1)	307 (81.4)	0.10
PsO family history, n (%)	341 (31.6)	243 (34.8)	98 (25.7)	0.003
PsA family history, n (%)	53 (4.9)	36 (5.1)	17 (4.5)	0.63
Inflammatory lower back pain, n (%)	275 (25.4)	155 (22.3)	120 (32.1)	0.002
Nail involvement, n (%)	503 (46.5)	314 (44.7)	189 (49.8)	0.21
Dactylitis, n (%)				
Ever	307 (28.4)	201 (30.0)	106 (29.1)	0.66
Current	72 (6.9)	43 (6.4)	29 (7.9)	
Enthesitis, n (%)				
Ever	225 (22.2)	143 (21.8)	82 (22.9)	0.36
Current	115 (11.4)	79 (12.1)	36 (10.1)	
RF[c] positive, n (%)	36 (5.4)	29 (6.6)	7 (3.1)	0.053
Anti-CCP[d] positive, n (%)	17 (4.6)	14 (5.4)	3 (2.7)	0.26
ANA[e] ⩾1/80 titre, n (%)	46 (8.5)	40 (10.9)	6 (3.5)	0.005

Available data included the age at PsA 1002, age at PsO 1004, current PsO lesion 1077, family history 1078, nail involvement 1080, dactylitis 1035, enthesitis 1012, inflammatory lower back pain 1023, ANA 538 and anti-CCP 328. PsO: psoriasis.

Table 2 The mean (S.D.) and median (range) values of patient- and physician-reported outcomes

Outcomes	All patients, mean (S.D.)	Female, mean (S.D.)	Male, mean (S.D.)	P-value
Patient-reported outcomes				
Duration of morning stiffness, n = 952	37.9 (43.0)	38.5 (43.8)	36.7 (41.6)	0.73
Patient global assessment (VAS), n = 733	43.5 (24.9)	44.3 (24.0)	42.1 (26.6)	0.22
Fatigue VAS, n = 750	46.2 (26.2)	48.5 (24.6)	42.0 (28.6)	0.002
Pain VAS, n = 756	44.6 (27.1)	45.5 (26.0)	43.1 (28.9)	0.21
HAQ, n = 699	0.71 (0.65)	0.74 (0.64)	0.66 (0.67)	0.014
BASDAI, n = 583	39.4 (25.6)	39.1 (24.5)	39.9 (27.3)	0.88
BASFI, n = 573	29.0 (24.2)	28.1 (23.7)	30.7 (24.9)	0.27
PSI, n = 409	7.5 (7.2)	7.4 (7.3)	7.7 (7.1)	0.57
Physician-reported outcomes				
Physician global assessment VAS, n = 679	35.6 (22.2)	35.6 (21.1)	35.8 (24.1)	0.86
Swollen joint counts, n = 1043	1.7 (3.0)	1.6 (3.1)	1.8 (2.8)	0.91
Tender joint counts, n = 1043	3.6 (4.8)	3.7 (5.0)	3.4 (4.3)	0.93
Body surface area, n = 406	6.1 (10.7)	4.9 (8.0)	8.4 (14.2)	0.69
Leeds enthesitis index, n = 1003	0.2 (0.7)	0.2 (0.8)	0.2 (0.5)	0.43
Composite index				
DAS-28, n = 693	3.47 (1.33)	3.61 (1.28)	3.21 (1.38)	<0.001

PSI: psoriasis symptom inventory; VAS: visual analog scale. (n) shows the number of patients with available data for that outcome.

Treatments

At the diagnosis of PsA, monotherapy [692 (76.1%)] was the most frequent treatment choice (Supplementary Table S1, available at *Rheumatology* Online). Two csDMARDs combination [189 (20.8%)] and triple csDMARDs combination [28 (3.1%)] were less frequently used treatment options. MTX [540 (59.4%)] and SSZ [105 (11.6%)] were the predominant choices for monotherapy. When patients who were diagnosed at the time of recruitment (inception cohort) were excluded, 87 (9.2%) patients were not receiving any csDMARDs or anti-TNF agents at the time of the visit. Treated patients were on the following regimens: csDMARD monotherapy 363 (38.6%), two csDMARD combination 187 (19.9%), triple csDMARD combination 25 (2.7%), anti-TNF monotherapy 67 (7.1%), anti-TNF plus one csDMARD 181 (19.2%), and

TABLE 3 Current percentage of minimal disease activity components

Minimal disease activity components	All patients, n (%)	Female, n (%)	Male, n (%)	P-value
Minimal disease activity (n = 247)	105 (42.5)	58 (38.6)	47 (48.4)	0.13
Swollen joint count ⩽1 joint (n = 1043)	698 (67.0)	463 (68.7)	235 (63.8)	0.11
Tender joint count ⩽1 joint (n = 1043)	450 (43.2)	292 (43.1)	158 (43.3)	0.97
Body surface area ⩽3% (n = 406)	235 (57.9)	167 (61.8)	68 (50.0)	0.022
Patient global assessment (VAS) ⩽20 (n = 733)	196 (26.7)	121 (25.3)	75 (29.4)	0.23
Pain (VAS) ⩽15 (n = 756)	132 (17.6)	74 (15.1)	58 (21.9)	0.013
HAQ ⩽0.5 (n = 699)	356 (50.9)	207 (47.7)	149 (56.2)	0.029
Enthesis ⩽1 (n = 1003)	65 (6.4)	43 (6.6)	22 (6.2)	0.79

VAS: visual analog scale.

anti-TNF plus two csDMARDs 31 (3.3%). A previous switch on anti-TNF drugs was present in 104 of 323 (32.2%) patients.

Differences between sexes

Women were significantly older than men at the time of the study as well as at the time of diagnosis (Table 1). Women had significantly more history of psoriasis in their family compared with men. They had more frequent peripheral arthritis than men and less axial disease [only peripheral *vs* axial *vs* combined, n (%): women 479 (68.5%), 62 (8.9%) and 158 (22.6%), respectively; men 222 (59.4%), 41 (11%) and 111 (29.7%), respectively; P = 0.011].

In terms of patient-related outcomes, women had more severe fatigue and their functional assessment was worse according to the HAQ scores. Despite having more fatigue, the women's perception of pain, GA and PSI for skin involvement were similar to those of men.

For physician-reported outcomes, all assessments were similar in both sexes. For MDA components, women had less skin involvement (according to body surface area ⩽3) and pain, but men had better function according to HAQ ⩽0.5 (Tables 2 and 3). Although the difference in MDA did not reach significance between women and men (38.6 *vs* 48.4% consecutively, P = 0.13), according to DAS28, women had higher disease activity [mean (S.D.) DAS28 for women 3.61 (1.28) and for men 3.21 (1.38); P < 0.001]. Also, the rate of remission was lower in women [n (%) of high, moderate and low disease activity and remission by DAS28: women 61 (13.6), 102 (22.8), 183 (40.8) and 102 (22.8); men 25 (10.2), 3 (1.2), 134 (54.7) and 83 (33.9); P < 0.001]. All the other clinical assessments were comparable for both sexes.

Discussion

The PsART is a multicentre, large, national cohort, for which we present the baseline demographic data, clinical features and treatment choices. Our registry had some similarities with the previously published registries, supporting its external validity.

Classically, five dominant disease patterns were defined in PsA in 1973 [18]. However, these patterns are not always clear and frequently overlap. In our patients, only one disease pattern was found in almost 60% of patients, with other patients having various types of combinations. Within joint patterns, we found that women had more frequent peripheral disease, whereas axial disease was more common among men [6, 7], similar to the previous literature. Unlike the previous studies that have shown that polyarticular involvement was predominant in women compared with an oligoarticular pattern in men, we did not observe the pattern differences for oligo- and polyarthritis between sexes [19, 20]. In 2002, the treatment choices of 1863 PsA patients from Germany were published, which were comparable to our registry, with the exception of biological treatments being higher in our registry, possibly because of the year of data collection and availability of the medications (29.6% were on biologics in PsART *vs* 2.1% in the German database) [21]. When we compared the treatment choices other than biologics, MTX (65.6 *vs* 65.9%) and low-dose glucocorticoids (25.9 *vs* 26.6%) were used at a similar rate, whereas SSZ (20.5 *vs* 12.0%) and HCQ (7.8 *vs* 2.7%) as well as a combination of more than one DMARD (22.6 *vs* 12.7%) were more frequently used in our registry. Fewer patients were not on any DMARDs in PsART (9.2 *vs* 16.1%). Our treatment choices were also compliant with the international recommendations. Both Group for Research and Assessment of Psoriasis and Psoriatic Arthritis [22] and EULAR [23] recommend synthetic DMARDs, especially MTX, as a first-line treatment option. In PsART, MTX was the most commonly used DMARD. Currently, two-thirds of PsA patients were still using MTX. Although HCQ is not part of the recommendations, a population-based cohort from the UK showed that 250 of 4155 (6.0%) PsA patients who were on DMARD had been prescribed HCQ [24]. Likewise, in PsART, currently 7.8% of patients had ever used HCQ, and mostly in combination with MTX. This result shows that although not a part of the recommendations,

rheumatologists prescribe HCQ for PsA. Given the high rate of cardiovascular co-morbidities in PsA, HCQ might have an added value for its positive effects on those, which requires further investigation. Another recommendation by EULAR is the use of DMARD combinations in the event of refractory disease. In our registry, almost 20% of patients used two or more DMARD combinations. Again, according to EULAR recommendations, in patients who fail to respond adequately to one anti-TNF agent, switching to another anti-TNF agent should be considered, which was almost one-third of patients in the PsART. Despite the majority of patients being on mono- or combined DMARD therapies and/or anti-TNF treatments, the cross-sectional analysis demonstrated that almost half of PsA patients had active disease status according to various outcome measures, such as pain and patient and physician GA. Our results illustrate the unmet need in PsA, and new treatment options could potentially overcome this need [25].

There were also some interesting differences between our registry and the previously published PsA cohorts. Gender was one of those differences. Almost two-thirds of PsART patients were women in our registry, despite the fact that psoriasis is equally prevalent in both sexes in our population, as shown in the Turkey psoriasis study [26]. PsA is slightly less frequent in women in some other cohorts; for instance, in CASPAR, GRACE and Toronto PsA cohorts, 43.2, 48.0 and 43.5% of patients, respectively, were women [9, 27, 28]. However, a population-based survey in Sweden found that PsA was slightly more frequent in women in all age groups [29]. As patients were consecutively recruited to our registry, a selection bias is not likely. Another reason would be the more frequent follow-up requirements of the women compared with men. A cross-sectional survey among 5604 patients with psoriasis and PsA in USA showed that female patients were 1.47 times more likely to seek care [30]. Our data showed that despite having similar objective disease activity parameters, as determined by the physician, women had more fatigue and their function loss was more significant. Also, women had higher DAS28 values as well as lower remission and low disease activity rates compared with men, which may indicate a higher unmet need in women. If women are more frequently seeking medical care, this could explain why women are more frequently recruited in a certain time frame. Supporting this, the inception cohort of newly diagnosed patients included fewer women then the whole group (64.7 *vs* 55.6%).

There are certain limitations of our cohort. Data were obtained from 32 centres, and heterogeneity of data may be considered a challenge in this kind of multicentre cohort. It is difficult to achieve a sufficient number of patients to be able to analyse all features of the disease in one centre. Additionally, if a high number of participants is obtained from only one centre, that has a risk of data coming only from a specialized clinic, therefore not being representative of routine practice. Missing data are another concern. Most of the demographic data, clinical features and treatment choices were missed in $<5\%$ of patients; however, missing data for the some of the outcome measures could be as high as 30%. The definition of disease patterns was according to the clinician. Axial disease was defined based upon the presence of inflammatory low back pain, which could have led us to miss patients who had subclinical disease, viewed as having significant sacroiliitis on X-ray and being negative for back pain. The lack of routine radiographic data collection in the whole group may have led to the misclassification of patients. However, asking for routine X-rays for patients with no clinical findings would be unethical and would not necessarily influence clinical decisions even in the face of positive findings.

There were also some strengths of the cohort. This is truly representative all the whole country, as almost all regions of Turkey contributed to the registry. The centres that participated in the trial are general rheumatology clinics without being specialized in PsA and are therefore more likely to represent general rheumatology practice. The number of patients recruited is very high, allowing a more accurate identification of disease characteristics. New diagnosis of PsA was present in almost 8% of our cohort, and a diagnosis of PsA for <1 year was present in 25%. Follow-up of those patients may provide additional information about the disease course. PSI has been used for the first time in a real-life setting with a large number of patients.

In conclusion, the PsART is a newly established national, multicentre PsA registry in Turkey. The baseline characteristics of this cohort are presented in this study. Female predominance is the major demographic difference from other cohorts. Clinical features were comparable to the other cohorts. Unfortunately, almost half of the patients had an active disease level, according to various outcome measures. Although 30% of patients currently use anti-TNF drugs, there is an unmet need because of an active disease state in a large number of patients. In future, follow-up of newly diagnosed PsA patients may bring additional insights about the disease course of PsA.

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Supplementary data

Supplementary data are available at *Rheumatology* Online.

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