EXTENDED REPORT

QUEST-RA: quantitative clinical assessment of patients with rheumatoid arthritis seen in standard rheumatology care in 15 countries

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Objective: To conduct a cross-sectional review of non-selected consecutive outpatients with rheumatoid arthritis (RA) as part of standard clinical care in 15 countries for an overview of the characteristics of patients with RA.

Methods: The review included current disease activity using data from clinical assessment and a patient self-report questionnaire, which was translated into each language. Data on demographic, disease and treatment-related variables were collected and analysed using descriptive statistics. Variation in disease activity on DAS28 (disease activity score on 28-joint count) within and between countries was graphically analysed. A median regression model was applied to analyse differences in disease activity between countries.

Results: Between January 2005 and October 2006, the QUEST-RA (Quantitative Patient Questionnaires in Standard Monitoring of Patients with Rheumatoid Arthritis) project included 4363 patients from 48 sites in 15 countries; 78% were female, >90% Caucasian, mean age was 57 years and mean disease duration was 11.5 years. More than 80% of patients had been treated with methotrexate in all but three countries. Overall, patients had an active disease with a median DAS28 of 4.0, with a significant variation between countries ($p<0.001$). Among 42 sites with >50 patients included, low disease activity of DAS28 $\leqslant 3.2$ was found in the majority of patients in seven sites in five countries; in eight sites in five other countries, >50% of patients had high disease activity of DAS28 >5.1.

Conclusions: This international multicentre cross-sectional database provides an overview of clinical status and treatments of patients with RA in standard clinical care in 2005–6 including countries that are infrequently involved in clinical research projects.

Quantitative assessment of patients with rheumatoid arthritis (RA) according to traditional measures such as laboratory tests, radiographs and joint counts, as well as patient questionnaires provides a valuable method to monitor patients in daily clinical practice. Quantitative clinical monitoring improves a doctor's ability to detect and document status and changes in patient's health condition, leading to greater precision in clinical decisions, and improved outcomes in patients with tight monitoring.[1–3] Quantitative measures are used in all clinical trials and other clinical research, but have not been widely incorporated into standard clinical care.[4]

Most of the scientific literature concerning quantitative measures of RA is based on randomised clinical trials. However, patients in clinical trials are highly selected for inclusion criteria, and may differ substantially from patients seen in standard care.[5–7] Therefore, data from clinical trials do not cover the spectrum of status of patients with RA at this time.

A number of clinical registries have been established over the last few years to monitor patients outside of clinical trials. Some local or nationwide databases monitor all types of patients with RA and other musculoskeletal conditions seen in standard care regardless of therapies.[8] However, many registries are limited to patients who receive biological therapies, some mandated by government and other funding agencies.

A need to collect further quantitative data concerning patients with RA seen in standard care in many settings in many countries led to the development of a programme to invite three or more sites in different countries to collect 100 patients with RA, as consecutively as possible. The objectives of the QUEST-RA (Quantitative Patient Questionnaire Monitoring Standard Clinical Care of Patients with Rheumatoid Arthritis) programme were (1) to enhance quantitative assessment of patients with rheumatic diseases in daily clinical practice and (2) to describe similarities and differences in the characteristics of patients with RA between countries, as presented in this report.

METHODS

QUEST-RA is an international effort to perform an identical cross-sectional review of 100 non-selected consecutive outpatients with RA in three or more rheumatology clinics in several countries starting in January 2005. The countries that had joined QUEST-RA by June 2006 are Denmark, Finland, France, Germany, Ireland, Italy, the Netherlands, Poland, Serbia, Spain, Sweden, Turkey, the UK, the USA and

Abbreviations: BMI, body mass index; DAS28, disease activity score on 28-joint count; DMARD, disease-modifying antirheumatic drug; ESR, erythrocyte sedimentation rate; HAQ, Health Assessment Questionnaire; QUEST-RA, Quantitative Patient Questionnaires in Standard Monitoring of Patients with Rheumatoid Arthritis; RA, rheumatoid arthritis; RF, rheumatoid factor

Argentina. The programme has also been initiated in Estonia, Greece, Hungary, Latvia, Lithuania, Macedonia, Canada and Russia; data from these countries will be included in future reports. Approval for the study was obtained from local Internal Review Boards or Ethics Committees, and all participating patients signed an informed consent.

Clinical evaluation

Patients were assessed according to a standard protocol to evaluate rheumatoid arthritis (SPERA).[9] The rheumatologists performed a clinical assessment involving a review of clinical features including classification criteria, extra-articular features, co-morbidities, relevant surgeries, all previous and present disease-modifying antirheumatic drugs (DMARDs), a 42-joint count[10] which includes swollen and tender joints, and joints with limited motion or deformity on a 28-joint count, and doctor global assessment of disease activity and erosive/non-erosive disease. Laboratory tests included erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP). The most recent rheumatoid factor (RF) values were collected; RF was considered positive if it was positive according to the local reference values at any time over the disease course. Lifetime use of DMARDs was calculated as the total number of years on DMARDs for each patient. Delay of a DMARD treatment was calculated as months between the start of symptoms and initiation of the first DMARD. No training was provided on how to collect data or to perform joint counts, and the study was intended to reflect routine clinical practice.

Patient self-report

The patients completed an expanded self-report health questionnaire that includes the Health Assessment Questionnaire (HAQ),[11] the multidimensional HAQ (MDHAQ),[12] HAQ II,[13] Recent-Onset Arthritis Disability (ROAD) questionnaire[14] and Rheumatoid Arthritis Disease Activity Index (RADAI) self-report joint count;[15] duration of morning stiffness; visual analogue scales (VAS) for pain, global status and fatigue; years of education; height and weight for body mass index (BMI); lifestyle choices such as smoking and physical exercise; and work status.

Translation of patient questionnaire

The patient questionnaire was translated into each language by local rheumatologists and translated back into English by professional translators. Possible discrepancies were discussed between local rheumatologists, study co-ordinators and translators until agreement, in order to ensure the meaning of the original questionnaire had been retained. In a few languages (Danish, Finnish and Swedish), an official back-translation was not performed but the questionnaire was translated by a team and piloted in the clinic to ensure that the meaning of the questions was correctly understood. A previous official translation of the HAQ was used in countries where it was available. In Dutch and Spanish, several translations of the HAQ were available which were incorporated into one official consensus version.[16]

Statistical methods

Descriptive data are presented as means with standard deviation (SD), medians with interquartile range and percentages. Variation in DAS28 (disease activity score on 28-joint count)[17 18] within and between countries is graphically presented; 42 sites that enrolled >50 patients were included in the analysis and six sites that enrolled <50 patients by the time of data analyses were excluded from the graphical presentation. Although similarities and differences among and between sites and countries are easily visually captured, a median regression model was applied to analyse whether there are statistically siginificant differences in the disease activity between countries when adjusted for age, sex, disease duration and RF (positive vs negative). A median regression model was chosen because it allows a skewed distribution of a studied variable.

RESULTS

Overall programme

Data collection was begun in January 2005. In October 2006, the QUEST-RA database included 4363 patients from 48 sites in 15 countries. Eight countries reached the goal to enrol a total of 100 RA patients from three or more sites by the time of data analysis (table 1).

Demographic characteristics

Overall, patients represent a typical RA cohort, with 78% females, 90% Caucasians, mean age of 57 years and a mean education level of 11 years (table 1). Females represented >85% of patients in Argentina, Serbia, Poland and Turkey. In European sites, patients were >95% Caucasians, except in France with 93% and the UK 83%. The youngest mean age, <55 years, was seen in Argentina, Turkey and Poland. The mean

Table 1 Patient characteristics in the QUEST-RA study by country

Country	No. of sites	No. of patients	Female %	Non-Caucasians %	Age, mean	Education years mean	BMI, female mean	BMI, male mean	Disease duration years mean	RF+ %	Extra-articular disease* %
Denmark	3	301	76.7	1.7	57.8	10.73	24.6	25.5	12.0	73.7	33.9
Finland	3	304	72.4	0.3	58.5	10.36	26.7	26.5	13.5	75.1	17.8
France	4	389	77.9	6.7	55.3	10.86	24.8	25.2	12.8	75.3	20.6
Germany	3	225	83.6	1.3	58.8	10.40	26.1	27.6	13.4	61.4	35.6
Ireland	3	225	64.3	3.1	56.7	11.59	25.3	25.5	11.5	81.0	29.9
Italy	4	336	78.2	0.9	61.0	8.34	25.2	26.0	10.5	72.7	13.0
The Netherlands	3	317	66.2	4.1	59.2	11.26	26.0	25.2	9.2	68.8	12.9
Poland	7	642	86.7	0.6	53.2	12.02	25.4	25.3	11.5	70.8	33.5
Spain	3	301	74.3	2.0	59.9	10.38	26.3	26.8	10.8	71.4	22.9
Sweden	3	248	72.1	1.2	59.5	10.42	25.2	25.3	12.4	82.0	22.6
UK	3	126	77.8	16.7	60.2	12.71	24.7	25.8	15.5	84.4	30.4
Turkey	3	309	85.6	2.9	51.9	7.37	27.3	26.4	11.6	68.7	18.1
Serbia	1	100	88.0	0	59.2	8.55	25.9	24.6	10.1	71.4	23.0
USA	3	294	72.3	32.4	57.4	13.49	28.2	27.9	9.3	69.9	24.1
Argentina	2	246	90.2	93.9	51.4	9.42	26.3	25.2	9.9	90.5	26.5
Total	48	4363	78.0	9.8	56.8	10.66	25.9	26.0	11.5	73.7	24.4

BMI, body mass index; QUEST-RA, Quantitative Patient Questionnaires in Standard Monitoring of Patients with Rheumatoid Arthritis; RF, rheumatoid factor.
*Includes nodules, pulmonal fibrosis, pericarditis, Felty's and scleritis.
A file including standard deviations of variables is provided in the supplementary material.

duration of education was <10 years in Turkey, Italy, Serbia and Argentina. Patients from the USA had the highest mean BMI values of 28.2 in females and 27.9 in males (table 1).

Disease characteristics

The mean duration of disease was 11.5 years; 74% of patients were positive for RF (table 1). One in four patients had extra-articular manifestations. The highest prevalence of extra-articular disease, >30%, was seen in Germany, Denmark, Poland and the UK; the lowest prevalence, <15%, was seen in the Netherlands and Italy (table 1).

Patient current clinical status

Patient clinical status was mildest in Denmark, Finland, the Netherlands and the USA, and most severe in Argentina, Serbia and Poland according to all clinical measures including ESR, joint counts, patient self-assessment and DAS28 (table 2). Overall, patients had an active disease with a median DAS28 of 4.0 with a significant variation between countries ($p<0.001$), adjusted for sex, age, disease duration and the presence of RF. Variation of disease activity per country and site is illustrated in fig 1; here 42 sites with >50 patients each are included. In seven sites in five countries, the majority of patients had low disease activity of DAS28 $\leqslant$3.2; in eight sites in five other countries, >50% of patients had high disease activity of DAS >5.1.

Use of DMARDs

The delay in starting a DMARD was longest in Germany, Spain and Argentina with a median of >12 months, and shortest in Poland and the Netherlands, at <6 months (table 3). Methotrexate appeared to be an anchor drug and was taken by >80% of patients at some time in all except three countries (Argentina, Serbia and the UK). A greater variability was seen in the use of glucocorticoids, and was highest at >80% of patients in Serbia and Argentina and lowest at <45% in the Netherlands and Denmark. Biological agents were used by >40% of patients in France and Ireland, and <10% of patients in Serbia, Argentina, Turkey and Poland. Lifetime use of DMARDs was highest in Finland, at 14.4 years, and lowest in Argentina, at 3.7 years (table 3).

DISCUSSION

The QUEST-RA study provides a general overview of patients with RA in standard clinical care in many countries, indicating similarities and differences in measures of disease activity, clinical status and the use of medications for RA. This general overview of patients with RA is of special value because it is a unique programme which has succeeded to date in describing clinical RA patients according to an identical protocol in various sites in various countries and various cultures.

Patients had an active disease with a median DAS28 of 4.0, with a significant variation between countries. In seven sites, >50% of patients had low disease activity according to the DAS28 values, and in eight sites the majority had high disease activity of DAS28 >5.1. Previous observations indicate that in many clinics a minority of patients are eligible for clinical trials due to low disease activity.[6 7] However, the present data suggest that a majority of patients seen in some clinics still have high RA disease activity at this time, and may possibly attract the interest of the pharmaceutical industry for inclusion in clinical trials.

Several registries have been established to collect clinical data on patients who receive biological agents, but they usually do not include patients who are taking other DMARDs. Therefore, relatively little is known regarding what percentage of patients under routine clinical care receive biological agents and other DMARDs. The QUEST-RA provides an overview of the use of DMARDs in different countries at this time, although in some countries QUEST-RA sites may not represent the whole country, which is a limitation of the study. In the US QUEST-RA sites, 33% of patients had taken biologics, which is a somewhat lower percentage compared with 42% in the National Data Bank in 2005.[19] In Germany, a much higher percentage (29%) of RA patients had taken biologics in the QUEST-RA sites, while only 5% were currently taking biologics in the national RABBIT database in 2002.[20] In France, >40% of patients were taking biologics because only tertiary centres participated in the programme. Further efforts are needed to expand the coverage of the programme.

The clinical picture of RA ranges from mild to severe, and may be influenced by genetic and environmental factors as well as treatments and treatment strategies. A need has been recognised to identify genetically and biologically different subgroups of patients with RA for clinical trials and for different treatment strategies.[21] In addition to the storage of clinical information, an international collaboration such as the QUEST-RA programme can provide a basis to collect biospecimens as well, in order to study the complicated interplay

Table 2 Median values of clinical variables in the QUEST-RA study by country

Country	ESR	SJC28 0–28	TJC28 0–28	LIM28 0–28	MDGlobal 0–10	HAQ 0–3	MDHAQ 0–3	Pain 0–10	Global 0–10	Fatigue 0–10	DAS28 0–10	%am15*
Denmark	14.0	1.0	2.0	0.0	1.3	0.63	0.50	2.6	2.8	3.6	3.3	56%
Finland	13.0	1.0	1.0	0.0	0.9	0.63	0.50	2.8	2.8	2.6	3.1	66%
France	16.0	1.0	2.0	1.0	2.5	0.88	0.60	3.9	3.6	4.2	3.6	60%
Germany	20.0	3.0	4.0	0.0	3.0	0.75	0.60	5.0	4.9	4.6	4.3	56%
Ireland	18.0	3.0	4.0	2.0	1.6	0.75	0.70	3.4	2.9	3.5	4.0	55%
Italy	28.0	2.0	4.0	0.0	3.0	1.06	0.80	4.9	5.0	4.9	4.5	51%
The Netherlands	15.0	1.0	0.0	1.0	0.6	0.75	0.60	2.5	2.7	3.1	3.0	49%
Poland	31.0	6.0	9.0	3.0	4.3	1.38	1.20	5.0	4.8	5.2	5.3	78%
Spain	17.0	1.0	1.0	0.0	1.2	0.88	0.72	3.2	3.6	3.7	3.5	47%
Sweden	19.0	2.0	2.0	1.0	1.3	0.88	0.70	3.3	3.3	3.7	3.6	67%
UK	21.0	1.0	4.0	0.0	2.0	0.88	0.70	4.2	3.8	5.1	4.2	65%
Turkey	30.0	0.0	2.5	0.0	2.0	0.88	0.70	4.2	4.6	4.5	4.1	53%
Serbia	28.0	6.0	18.0	2.0	4.6	1.63	1.40	5.1	5.3	5.5	6.1	71%
USA	14.0	2.0	1.0	0.0	1.9	0.63	0.56	3.3	2.6	3.2	3.2	58%
Argentina	30.0	9.0	10.5	2.0	4.6	1.00	0.90	5.0	4.7	6.3	5.6	64%
Total	21.0	2.0	3.0	1.0	2.2	0.88	0.70	4.0	4.0	4.4	4.0	61%

DAS28, disease activity score on 28-joint count; ESR, erythrocyte sedimentation rate; HAQ, Health Assessment Questionnaire; LIM, limited motion/deformity joint count; MDGlobal, Doctor Global Assessment of Disease Activity; MDHAQ, multidimensional HAQ; QUEST-RA, Quantitative Patient Questionnaires in Standard Monitoring of Patients with Rheumatoid Arthritis; SJC, swollen joint count; TJC, tender joint count.
*Percentage of patients who report morning stiffness of 15 min or more.
A file including the interquartile ranges of variables is provided in the supplementary material.

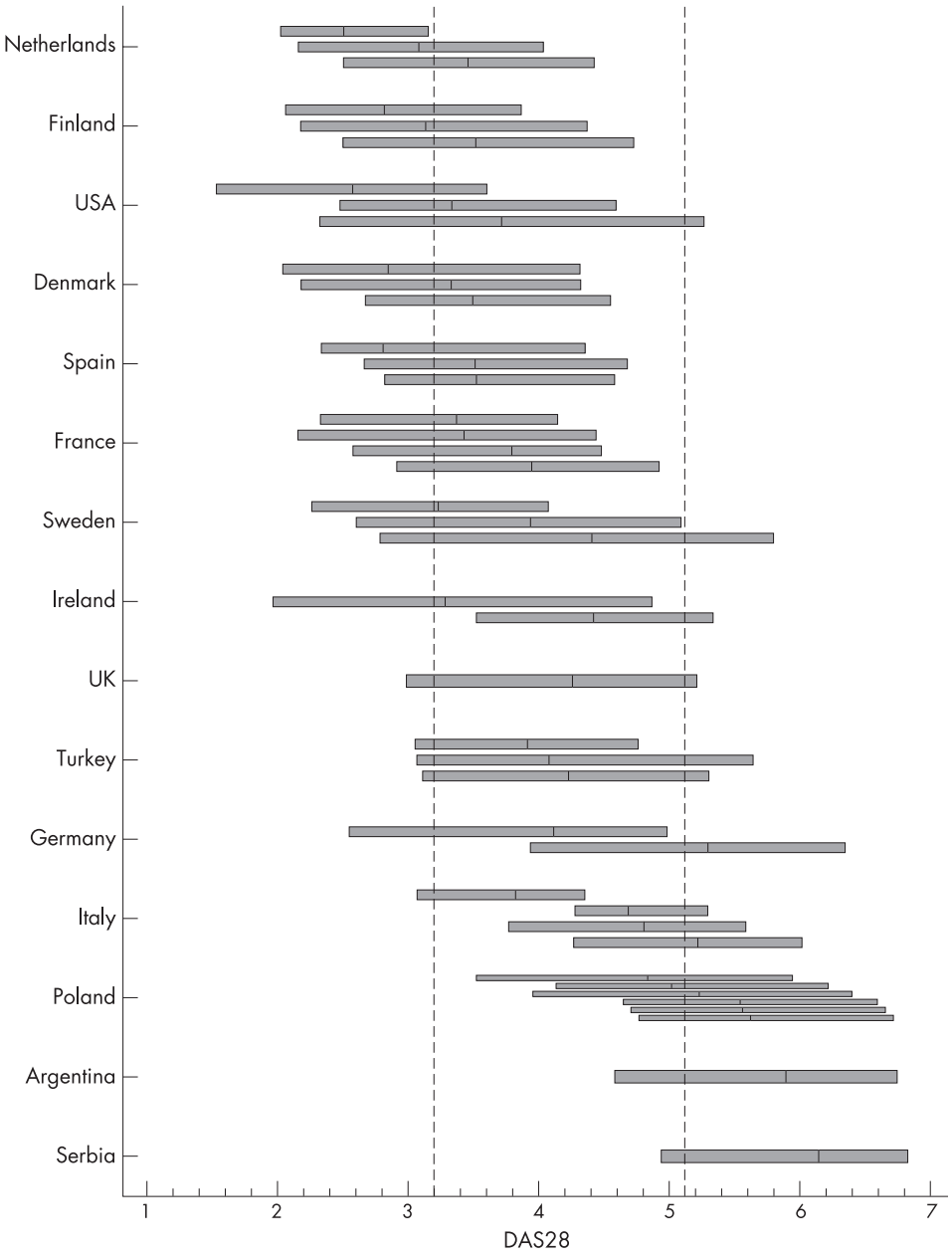

Figure 1 Disease activity according to DAS28 (disease activity score on 28-joint count; median, interquartile range) in QUEST-RA by country and site. Reference lines indicate low (DAS28 $\leqslant$3.2) and high (DAS28 $>$5.1) disease activity.

between genetic and environmental factors in the development, responses to treatments and overall clinical picture of RA.

Quantitative assessment of RA in standard clinical care is valuable to assess status and help guide therapies. In addition, it provides opportunities for comparison of groups of patients to improve knowledge of diseases beyond clinical trials. The QUEST-RA programme should further enhance introduction of quantitative assessment into standard care of patients with rheumatic diseases in many locations, many countries and many cultures.

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Table 3 The use of disease-modifying antirheumatic drugs (DMARDs) in the QUEST-RA countries; the highest percentage for each drug is indicated in bold, and the lowest in bold italics

Country	Delay to start DMARDs, months, median	DMARD exposure years, mean	Selected DMARDs ever taken; percentage of patients in the QUEST-RA study per country					
			Pred	MTX	HCQ	SSZ	LEF	Any biological agent
Denmark	10	7.9	43%	85%	39%	64%	11%	23%
Finland	7	14.4	74%	85%	**74%**	**84%**	21%	17%
France	8	9.9	83%	86%	55%	49%	**42%**	**53%**
Germany	15	8.4	54%	78%	30%	36%	25%	29%
Ireland	11	6.3	71%	**92%**	***15%***	33%	24%	41%
Italy	9	7.1	69%	79%	42%	14%	31%	26%
The Netherlands	5	8.1	***26%***	91%	28%	35%	6%	19%
Poland	4	7.2	69%	87%	34%	60%	18%	8%
Spain	14	7.3	67%	82%	43%	29%	34%	27%
Sweden	12	8.8	66%	83%	34%	62%	9%	31%
UK	12	7.9	51%	***67%***	39%	46%	***4%***	16%
Turkey	12	8.9	69%	88%	27%	61%	22%	7%
Serbia	11	6.6	**88%**	69%	55%	17%	7%	***2%***
USA	9	7.9	77%	85%	49%	12%	19%	33%
Argentina	13	3.7	83%	68%	49%	***6%***	16%	3%
Total	9	8.1	66%	83%	41%	43%	21%	23%

HCQ, hydroxychloroquine; LEF, leflunomide; MTX, methotrexate; Pred, prednisone; QUEST-RA, Quantitative Patient Questionnaires in Standard Monitoring of Patients with Rheumatoid Arthritis; SSZ, sulfasalazine.
A file including the standard deviation of DMARD exposure and the interquartile range of the delay to starting DMARDs is provided in the supplementary material.

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