BRIEF REPORT



Usage of C-Reactive Protein Testing in the Diagnosis and Monitoring of Psoriatic Arthritis (PsA): Results from a Real-World Survey in the USA and Europe

A. Ogdie \cdot W. Tillett \cdot N. Booth \bigcirc \cdot O. Howell \cdot A. Schubert \cdot

S. Peterson · S. D. Chakravarty · L. C. Coates

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ABSTRACT

Introduction: C-reactive protein (CRP) is an important non-specific marker of both acute and chronic inflammation and can be elevated in patients with psoriatic arthritis (PsA). However, the use of CRP testing in the management of PsA can vary. This study investigated how CRP testing is implemented in real-world clinical practice for disease management of PsA. *Methods*: A point-in-time survey of rheumatologists and dermatologists and their next six

A. Ogdie Perelman School of Medicine, Philadelphia, USA

W. Tillett University of Bath, Bath, UK

N. Booth (⊠) · O. Howell Adelphi Real World, Bollington, UK e-mail: nicola.booth@adelphigroup.com

A. Schubert Janssen-Cilag, Warsaw, Poland

S. Peterson Janssen Global Services, LLC, Raritan, USA

S. D. Chakravarty Janssen Scientific Affairs, LLC, Titusville, USA

S. D. Chakravarty Drexel University College of Medicine, Philadelphia, USA

L. C. Coates University of Oxford, Oxford, UK consulting patients with PsA was conducted in France, Germany, Italy, Spain, UK (EU5), and the USA between June and August 2018. Use of CRP testing was obtained by asking the physician to state (yes/no) whether CRP was used to aid PsA diagnosis and/or to monitor the patient's disease activity. The number of CRP tests conducted in the last 12 months for each patient enrolled was provided.

Results: Data were collected for 2270 patients (USA, *n* = 595; EU5, *n* = 1675). In the EU5, CRP testing was conducted to aid diagnosis in 78.7% of patients (vs. 43.4% in USA) and CRP was used to monitor disease activity in 72.0% (vs. 34.6% in USA). The majority (80.9%) of patients in the EU5 had at least one CRP test in the last 12 months compared to 42.9% in the USA. Patients treated by rheumatologists (vs. dermatologists) were at least 50% more likely to have CRP tested for monitoring purposes, this difference being most pronounced in the USA. In the EU5, CRP testing was conducted a mean \pm standard deviation of 2.7 \pm 1.7 times during the last 12 months, versus 2.0 ± 1.4 in the USA.

Conclusions: CRP was more commonly used for the diagnosis and monitoring of PsA in Europe compared to the USA and was more commonly ordered by rheumatologists than dermatologists. In the absence of a better serum biomarker of inflammation, more data are needed to understand how CRP testing should be used in the diagnosis and management PsA. **Keywords:** Psoriatic arthritis; Inflammation; C-reactive protein; Testing patterns; Real world evidence

Key Summary Points

Why carry out this study?

While C-reactive protein (CRP) levels can be elevated in patients with psoriatic arthritis (PsA), the use of CRP testing in the management of PsA can vary

This study investigated how CRP testing for the diagnosis and monitoring of PsA is implemented in real-world clinical practice

What was learned from the study?

CRP testing was more commonly used for diagnosis and monitoring of PsA in Europe than in the USA

CRP testing was more commonly used by rheumatologists than dermatologists

In the absence of a better serum biomarker of inflammation, more data are needed to understand how CRP testing should be used in the diagnosis and management PsA

INTRODUCTION

C-reactive protein (CRP) is an important nonspecific marker of both acute and chronic inflammation. However, while CRP values are known to be elevated in a proportion of patients with psoriatic arthritis (PsA) [1], and are associated with worse disease severity and symptomatic burden, many patients with PsA do not have raised CRP levels, despite having active inflammation.

CRP testing is inexpensive and accessible, however, its utility as a marker of interest in inflammatory conditions including PsA can vary [2]. There is relative uncertainty surrounding its reliability, validity as a marker of disease activity, and its prognostic value. Despite this uncertainty, CRP testing is a part of several key composite outcome measures, including the American College of Rheumatology Response Criteria, the primary outcome in PsA clinical trials, and the Disease Activity of Psoriatic Arthritis (DAPSA) score, as well as rheumatoid arthritis outcome measures commonly employed in PsA (i.e., Disease Activity Score-28 [DAS28]) [3]. There is wide variability in the use of CRP across physicians monitoring psoriatic disease, including in PsA management, and variable ability to have laboratory values at the time of the clinic visit. The objective of this study was to investigate how CRP testing is implemented in real-world clinical practice for disease management of PsA.

METHODS

Data were drawn from the Adelphi PsA Disease Specific Programme (DSPTM), a large, multinational point-in-time survey of rheumatologists and dermatologists and their consulting patients in a real-world clinical setting. This survey was conducted in Europe (France, Germany, Italy, Spain, UK; i.e., EU5) and the USA between June and August 2018. A complete description of the survey methodology has previously been published and validated [4]. A geographically diverse sample of physicians were recruited across different sites and settings in order to generate a sample reflective of current clinical practice across all regions and territories.

Physicians were eligible to participate if they had 3–30 years of experience and were personally and directly responsible for the management of patients with PsA. Physicians completed patient record forms for up to their next six consecutive consulting patients; these visits could be for diagnosis or monitoring purposes, but were all related to the management of PsA. Patients were eligible for inclusion if they visited a participating physician, had a diagnosis of PsA, were aged \geq 18 years, and were not currently involved in a clinical trial. There was no restriction by treatment received. Completion of these forms was undertaken through consultation of existing patient clinical records, as well as the judgement and diagnostic skills of the respondent physician, consistent with decisions made in routine clinical practice. Missing data were not imputed; therefore, the base of patients for analysis could vary from variable to variable and is reported separately for each analysis.

Use of CRP testing was obtained by asking the physician to state (yes/no) whether CRP was used to aid PsA diagnosis, confirm the patient's PsA, and/or to monitor the patient's PsA, with the selection made according to physician judgement in consultation with the patient's clinical chart history. Where physicians stated use of CRP testing, they were then asked to provide the number of CRP tests conducted in the last 12 months, as well as the reason for conducting the test (either for monitoring or diagnostic purposes). Currently prescribed disease-modifying antirheumatic drug (DMARD) treatment usage was also recorded. Severity of disease was reported by physicians who classified their patients as having mild/moderate/severe disease based on their own judgement.

Data collection was undertaken in line with European Pharmaceutical Marketing Research Association guidelines [5], and as such did not require ethics committee approval. However, ethical approvals were sought and granted through the Freiburg Ethics Commission in Europe (study code: 02018/1077) and Western Institutional Review Board in the USA (study number: 1183030). Each survey was performed in full accordance with relevant legislation at the time of data collection, including the US Health Insurance Portability and Accountability Act 1996 [6], and Health Information Technology for Economic and Clinical Health Act legislation [7]. Data were collected in such a way that patients and physicians could not be identified directly; all data were aggregated and de-identified before receipt, and informed consent was given.

The analysis involved descriptive statistics and, where appropriate, the proportion of patients (number and percentage) or mean values with standard deviation (SD) were reported.

RESULTS

Data were collected for 2270 patients with PsA (USA, n = 595; EU5, n = 1675), with an even split between those treated by dermatologists (n = 1140) and rheumatologists (n = 1130). The mean age \pm SD was 48.6 \pm 13.3, 90% of patients were Caucasian, and 46% were female. Three quarters (75%) of patients were classified with mild disease, with 25% of patients having moderate/ severe disease (Table 1). The mean body mass index (\pm SD) was 26.8 \pm 4.7 (EU5, 26.3 \pm 4.3 kg/m²; USA, 28.1 \pm 5.5 kg/m²), 20.3% of patients were smokers (EU5, 24.3%; USA, 9.5%,), and 58.2% were working full-time (EU5, 55.6%; USA, 65.3%).

Regarding treatment use, just over half (54.2%) of all patients in the USA and EU5 received a biologic DMARD (bDMARD), 11.1% of patients received a targeted synthetic DMARD (tsDMARD; EU5, 7.2%; USA, 21.8%), and 36.8% received a conventional synthetic DMARD (csDMARD; EU5, 41.7%; USA, 23.0%) at the time of data collection (Table 1). Of those receiving csDMARDs, 14.9% were in combination with b/tsDMARDs (EU5, 16.3%; USA, 10.9%) and 21.9% were as the highest level of treatment (EU5, 25.4%; USA, 12.1%). On average, patients visited a physician 6.5 times a year (mean \pm SD visits in past 12 months: EU5, 7.0 \pm 6.3; USA, 5.0 \pm 3.6).

Use of CRP testing varied between regions, with the majority (80.9%) of patients with PsA in the EU5 having at least one CRP test in the last 12 months, compared with 42.9% in the USA. On average over the past 12 months, CRP testing was conducted more frequently in the EU5 (mean \pm SD: 2.7 \pm 1.7 times) compared to the USA (2.0 \pm 1.4 times) (Table 1). Use of CRP testing also varied by physician specialty. A greater number of rheumatologists than dermatologists used CRP testing to aid in diagnosis (82 vs. 57%), to confirm PsA diagnosis (44 vs. 27%), and to monitor PsA (78% vs. 46%); however, the proportions of reported reasons for testing between physician specialities were similar (Fig. 1). The differences previously noted in CRP testing usage between regions was also evident across physician specialities, with

Patient demographic and clinical characteristics	Overall $(n = 2270)$	EU5 $(n = 1675)$	USA $(n = 595)$
Patient seen by rheumatologist, <i>n</i> (%)	1130 (49.8)	834 (49.8)	296 (49.7)
Age, years, mean [SD]	48.6 [13.3]	48.1 [13.1]	50.0 [13.5]
Female, n (%)	1047 (46.1)	774 (46.2)	273 (45.9)
BMI, kg/m ² , mean [SD]	26.8 [4.7]	26.3 [4.3]	28.1 [5.5]
Caucasian, n (%)	2051 (90.4)	1551 (92.6)	500 (84.0)
Current smoker, n (%)	403 (20.3)	352 (24.3)	51 (9.5)
Employment status, n (%)			
Working full-time	1271 (58.2)	894 (55.6)	377 (65.3)
Patient insurance type, n (%)			
GesetzlicheKrankenversicherung (Germany)		335 (20.0)	
Sistema Nacional de Salud (Spain)		333 (19.9)	
Servizio Sanitario Nazionale (Italy)		305 (18.2)	
National Health System (UK)		303 (18.1)	
PUMa + CMU-C, mutuelle or assurance privée (France)		116 (6.9)	
Protection Universelle Maladie (PUMa) (France)		87 (5.2)	
Commercial insurance			405 (68.1)
Medicare			96 (16.1)
Health insurance exchange plan			40 (6.7)
Medicaid (or equivalent)			26 (4.4)
Other		196 (11.7)	28 (4.7)
Current disease severity, n (%)			
Mild	1702 (75.0)	1253 (74.8)	449 (75.5)
Moderate/severe	568 (25.0)	422 (25.2)	146 (24.5)
Current treatment, n (%)			
Receiving bDMARD	1231 (54.2)	910 (54.3)	321 (53.9)
Receiving tsDMARD	251 (11.1)	121 (7.2)	130 (21.8)
Receiving csDMARD	835 (36.8)	698 (41.7)	137 (23.0)
In combination with b/tsDMARD	338 (14.9)	273 (16.3)	65 (10.9)
As highest level of treatment	497 (21.9)	425 (25.4)	72 (12.1)
Receiving opioid	55 (2.4)	29 (1.7)	26 (4.4)

Table 1 Patient demographic and clinical characteristics

Patient demographic and clinical characteristics	Overall $(n = 2270)$	EU5 $(n = 1675)$	USA $(n = 595)$
Total number of HCP visits in last 12 months, mean [SD]	6.5 [5.8]	7.0 [6.3]	5.0 [3.6]
Frequency of CRP testing			
Patients with ≥ 1 CRP in last 12 months, n (%)	1610 (70.9)	1355 (80.9)	255 (42.9)
Number conducted in last 12 months, mean [SD]	2.5 [1.7]	2.7 [1.7]	2.0 [1.4]

Table 1 continued

bDMARD Biologic DMARD, csDMARD conventional synthetic DMARD, CRP C-reactive protein, DMARD diseasemodifying antirheumatic drug, HCP healthcare provider, SD standard deviation, tsDMARD targeted synthetic DMARD

uptake of testing by rheumatologists and dermatologists to aid diagnosis, confirm PsA diagnosis, and monitor PsA all being lower in the USA than in the EU5 (Fig. 1).

DISCUSSION

C-reactive protein is an accessible marker of non-specific inflammation, and CRP testing and can be used for monitoring PsA. However, while elevated CRP levels are associated with worse symptomatic burden in some patients and accelerated disease progression [1], CRP is not always elevated in patients with PsA and active disease. We found that the use of CRP in clinical practice varies depending on physician specialty and region, likely reflecting lack of standardization in the use of CRP testing for PsA management.

The relationship between systemic inflammation and CRP is complex, with CRP levels associated with the risk for cardiovascular disease, diabetes, metabolic syndrome, pulmonary diseases, and depression [8]. Adiposity has also

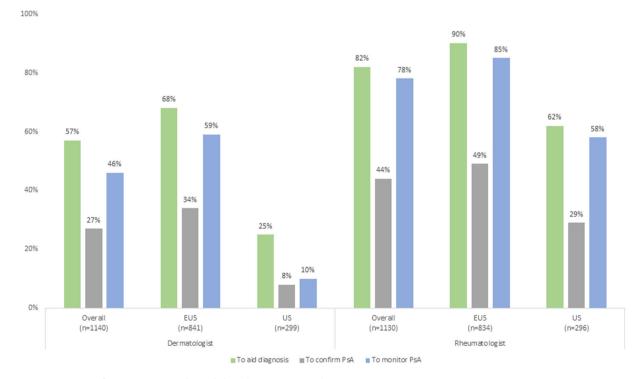


Fig. 1 Purpose of CRP tests conducted, by physician speciality

been shown to be associated with elevated CRP levels [9]; the association with obesity and both psoriasis and PsA is well established [10], and obesity may be related to the transition from psoriasis (PsO) to PsA [11]. All of these may explain why interpreting CRP levels in patients with inflammatory conditions, in particular around diagnosis, monitoring, disease progression, and risk stratification, can be challenging.

In psoriatic disease, CRP levels have been associated with psoriasis severity (i.e., patients with Psoriasis Area and Severity Index score > 12 on average had a higher CRP) [12]. CRP may also help differentiate PsA from psoriasis without PsA [13]. Among patients with established PsA, studies have found that elevated CRP levels at baseline are associated with a higher likelihood of developing radiographic damage over time, indicative of accelerated disease progression [14, 15]. Additionally, patients with consistently normal CRP levels over time have generally been found to have milder disease or less structural damage over time [16]. Finally, using data from randomized controlled trials, CRP levels may also be useful for assessing therapeutic response in PsA, though these data are limited [3, 12, 17].

CRP testing is frequently used in the management of rheumatoid arthritis, a related disorder that is often assessed and treated similarly. It is thus not surprising that the use of CRP testing in clinical practice was more common amongst rheumatologists compared to dermatologists in this study, which may be in part due to reasons of awareness, education, and comfort with the CRP testing process or time available for checking and reviewing the results of laboratory tests. It could be argued that physicians undertake differing roles in the diagnosis and management of PsA, with rheumatologists more orientated towards diagnosis and dermatologists towards management; however, we would still expect both specialities to assess CRP levels as part of a broader set of tests. While we do not report on the reason for patient visit to the physician at the point of recruitment, we do report on the number of tests undertaken over the preceding 12-month period, as well as the reasons these tests were performed (either for diagnostic or monitoring purposes), with the relative proportions of reported reasons for testing between physician specialities being broadly similar.

Additionally, use of CRP testing was more common in Europe than in the USA. This may be related to challenges in getting laboratory values in the USA given different electronic medical records and differing insurance coverage of laboratory venues. Patients in the USA had a range of insurance statuses, which could impact on the reduced level of testing observed in this region. While CRP testing is relatively inexpensive, the therapeutic options available may not be reimbursed or affordable if the patient has no insurance coverage, and thus physicians and their consulting patients in the USA may conclude that CRP testing is not worthwhile or that it is not required to be conducted as frequently as we observed in Europe, given the potential for considerable out-ofpocket expense.

LIMITATIONS

Physicians were asked to provide data on their next six consulting patients, in order to mitigate against selection bias. Physicians completed the record forms with access to the patient's historical medical records, with data collected at the time of consultation to limit recall bias. However, while the sample is representative of the consulting patient population, patients visiting their physician may be more severely affected than those who do not consult their physician as frequently. Data collection relied on the judgement and diagnostic skills of the respondent physician, which meant that responses to questions could be open to interpretation; however, this is consistent with decisions made in real world clinical practice.

CONCLUSION

The use of CRP testing for diagnosis and monitoring of PsA in clinical practice varied widely, with more frequent use across Europe than in the USA, and greater uptake by rheumatologists than dermatologists. Despite its limitations, CRP remains the only currently available biomarker of inflammation, and should be used alongside other measures of disease activity, such as joint counts, to either confirm diagnosis or monitor changes in disease status. Additional studies are needed to identify other potential biomarkers in PsA and to better understand the interpretation and use of CRP testing in the diagnosis and management of PsA, not only in the USA and Europe but also in emerging markets where the use of CRP testing may not be as established.

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Data Availability. Data collection was undertaken by Adelphi Real World as part of an independent survey, entitled the Adelphi Psoriatic Arthritis Disease Specific Programme (DSP). The DSP is a wholly owned Adelphi product. All data, i.e., methodology, materials, data and data analysis, that support the findings of this survey are the intellectual property of Adelphi Real World. All requests for access should be addressed directly to Nicola Booth (nicola.booth@adelphigroup.com).

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