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Original article

Performance of the 2015 ACR-EULAR classification criteria for gout in a primary care population presenting with monoarthritis

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Abstract

Objective. To test the performance of the 2015 ACR-EULAR gout classification criteria against presence of SF MSU crystals in a primary healthcare population.

Methods. The criteria were applied to an existing dataset of consecutive patients with monoarthritis presenting to Dutch family physicians; all patients underwent microscopic SF analysis by design. The data had been prospectively collected to develop a diagnostic decision rule for gout in 2010. Diagnostic performance was assessed by calculating area under the receiver operating characteristic curve, sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and constructing calibration plots for the full version of the criteria (including SF analysis results of all patients) and the clinical-only version (not including SF analysis results). Performance of both versions was compared with the 2010 diagnostic rule.

Results. Of 381 patients enrolled into the study, 216 (57%) were MSU crystal-positive. The full and clinical-only versions of the criteria had satisfactory area under the receiver operating characteristic curve (0.96 and 0.87, respectively), high specificity (0.98 and 0.84), high PPV (0.98 and 0.84), but lower sensitivity (0.68 and 0.68) and NPV (0.70 and 0.67). Specificity and PPV of both versions were higher compared with 0.71 and 0.89 of the 2010 diagnostic decision rule. The decison rule had the highest sensitivity and NPV (0.99 and 0.97).

Conclusion. This study presents the first external validation of the 2015 ACR-EULAR gout classification criteria in a primary healthcare setting. The criteria perform well in this setting in patients presenting with monoarthritis for the purpose of enrolling into gout clinical trials.

Key words: gout, classification criteria, primary healthcare

CLINICAL SCIENCE

Rheumatology key messages

- The 2015 ACR-EULAR gout classification criteria performed well in primary care for enrolling patients into clinical trials.
- More sensitivity of the 2015 ACR-EULAR criteria would be advantageous for performing epidemiological studies in primary care.
- The 2015 ACR-EULAR gout criteria are intended for classifying study participants, not for making diagnoses in medical practice.

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Introduction

Gout is the commonest cause of inflammatory arthritis in men and is increasing in prevalence [1, 2]. Most patients with gout are treated in primary care settings, where gout diagnoses are made mainly without using the gold standard of microscopic identification of MSU crystals in aspirated joint fluid. Hence, if potential patients with gout need to be classified, for example, for clinical trial recruitment, classification criteria for gout need to be applicable in that context [3, 4].

The 2015 ACR-EULAR classification criteria for gout were developed using a multi-phase process, including a multi-attribute decision analytic approach by a group of experts in the field of gout and of gout research that included mainly rheumatologists and a few primary care physicians [3, 4]. Many of the data that informed the opinion of this group were based on a diagnostic study of patients with arthritis who were included in the Study for Updated Gout Classification Criteria (SUGAR) study (January 2013 to April 2014) and who were all tested for the presence of MSU crystals in a rheumatology clinic setting [5, 6]. The 2015 ACR-EULAR criteria were shown to have acceptable specificity (0.95) and sensitivity (0.92) when internally validated in this population, and also if using only clinical parameters, that is, without scoring results of MSU identification and imaging (0.89 and 0.85, respectively). However, it is necessary to confirm the performance of the criteria externally, particularly in a primary care setting. This study examines the performance of the 2015 ACR-EULAR gout criteria in a primary care sample of consecutive patients presenting with acute monoarthritis, who were all tested for the presence of MSU crystals.

Methods

For the purpose of this study we used existing data that had been prospectively collected to develop a primary care diagnostic decision rule for the presence of MSU crystals in joint fluid of patients presenting acute monoarthritis (the 2010 Gout Diagnostic Decision Rule; see supplementary Table S1, available at *Rheumatology* Online). The details of the original study (patient inclusion 2004–07, eastern part of the Netherlands) have been reported previously [7]. Briefly, patients with monoarthritis consecutively recruited by family physicians in their daily primary healthcare practice were immediately sent to one regional rheumatology research centre and evaluated by a rheumatologist using standard case record forms. At this first presentation (within 24 h of visiting the family physician), SF was obtained from the affected joint of each patient and analysed by an experienced and certified observer (M.J.) for the presence of MSU crystals by polarizing light microscopy. If MSU crystals were not detected, and a type of arthritis other than gout was diagnosed (such as septic arthritis, calcium pyrophosphate deposition disease, PsA and ReA), patients were not followed any more. If at the initial presentation neither MSU crystals could be identified, nor other types of arthritis could be diagnosed (undifferentiated arthritis) patients were followed for at least 1 year. In the case of a recurrent attack, microscopic SF analysis and diagnostic re-evaluation by protocol were repeated. Patients were defined as MSU crystal-positive if MSU crystals were identified at the first presentation or on any occasion over the follow-up period (initially false-negative). Patients were considered to be MSU crystal-negative in all other cases.

Because some of the data collected regarding clinical items did not exactly match the 2015 ACR-EULAR categories, the criteria items were mapped to items available in the existing primary care dataset. Each of the mapped items was checked and scored according to the rules shown in Table 1. Imaging items were not available and were therefore scored 0, as per the 2015 ACR-EULAR recommended scoring absent or not done. Because all patients in the original primary care study underwent SF analysis, we modified the scoring of the domain item SF analysis by elaborating two versions as follows. First, a full version, in which this item was scored as 0 (as per the standard scoring SF analysis not done) if MSU crystals were present (otherwise further application of the 2015 ACR-EULAR criteria would not have been necessary, since presence of MSU crystals is technically sufficient for classification by these criteria), and –2 [as per the scoring SF analysis of a symptomatic (ever) joint or bursa (should be assessed by a trained observer) *and* MSU negative] if MSU crystals were not present. Second, a clinical-only version in which the item SF analysis was not included in the analysis and scored 0 for all cases (as per the scoring SF analysis not done), mimicking the daily practice of primary care, where SF analysis is very infrequently performed.

The performance of the two versions of the criteria was assessed using the area under the curve of a receiver operating characteristic curve, sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) at a threshold for classifying gout with a score of 8 or more, as per the published criteria [3, 4]. Calibration plots for the full and clinical-only versions of the 2015 ACR-EULAR criteria were constructed from the Hosmer–Lemeshow goodness-of-fit contingency tables.

Both versions were compared with the previously developed 2010 Gout Diagnostic Decision Rule, which was derived in this same dataset. Numbers and proportions of MSU crystal-positive or MSU crystal-negative cases meeting each category of criteria were tabulated together with age and gender characteristics.

This study was approved by the regional ethics review committee (Arnhem-Nijmegen) after patients in the 2010 original primary care study gave written permission to use their data anonymously for future research.

Results

Patient characteristics are shown in Table 2. There were 381 patients with monoarthritis recruited by 93 family physicians, of whom 216 (57%) were MSU crystal-positive, including seven patients whose initial microscopy did not show MSU crystals (initially false-negative),

TABLE 1 Mapping of the studied items to the ACR-EULAR criteria

Domains ACR-EULAR criteria	Clinical categories ACR-EULAR criteria	Clinical items in studied dataset	ACR-EULAR score
Pattern of joint/bursa involvement in symptomatic episode(s) ever	Joint(s) or bursa(e) other than ankle, midfoot or first MTP1 (or their involvement only as part of a polyarticular presentation	Not necessary[a]	Score 0
	Ankle OR midfoot (as part of oligo/monoarticular episode)	Ever involved joint was ankle or between ankle and MTP joints	Score 1
	MTP1 (as part of oligo/monoarticular episode)	Ever involved joint was MTP1	Score 2
Characteristics of symptomatic episode(s) ever	Erythema overlying affected joint (patient-reported or physician-observed)	Present affected joint was red (patient reported or physician observed)	One item Score 1 Two items Score 2 Three items Score 3
	Cannot bear touch or pressure to affected joint	Patient reported present pain VAS (0–100 mm) was >50	
	Great difficulty with walking or inability to use affected joint	Patient reported present difficulty with using affected joint VAS (0–100 mm) was >50	
Time course of symptomatic episode(s) ever	Time to maximal pain <24 h	Onset <1 day in the presenting episode	All items during one episode Score 1
	Resolution of symptoms in ⩽ 14 days	Resolution of symptoms <3 weeks (maximum) following presenting episode	
	Complete resolution (to baseline level) between symptomatic episodes	Resolution of symptoms <3 weeks (maximum) following presenting episode	
	Recurrent typical episodes	Previous patient-reported arthritis attack[b]	Score 2
Clinical evidence of tophus	Subcutaneous draining or chalk-like nodule under transparent skin with overlying vascularity, located in typical locations: ears, olecranon bursa, finger pads, tendon (e.g. Achilles)	Tophus observed	Score 4
Serum urate level (measured by uricase method): mg/dl (mmol/l)	Ideally should be scored at a time when the patient was not taking urate-lowering treatment and patient was beyond 4 weeks of the start of an episode (i.e. during intercritical period); *if* practicable, retest under those conditions. The highest value irrespective of timing should be scored	Tested in the presenting episode, irrespectively of the use of urate lowering drugs	
	<4 (0.24)	<4 (0.24)	Score −4
	4 (0.24) to < 6 (0.36)	4 (0.24) to < 6 (0.36)	Score 0
	6 (0.36) to < 8 (0.48)	6 (0.36) to < 8 (0.48)	Score 2
	8 (0.48) to < 10 (0.60)	8 (0.48 to < 10 (0.60)	Score 3
	⩾10 (0.60)	⩾10 (0.60)	Score 4
SF analysis	SF analysis of a symptomatic (ever) joint or bursa (should be assessed by a trained observer) *and* MSU negative	SF analysis by a trained rheumatologist observer in presenting episode *and* MSU negative	Score −2
	SF analysis not done	Not applicable (SF analysis of all patients)	Score 0
Imaging evidence of urate deposition (by US or DECT)	US and DECT not done	Not available = not done	Score 0
	Urate deposition absent		Score 0
	Urate deposition present		Score 4
Imaging evidence of gout-related joint damage (by radiography)	Radiography not done	Not available = not done	Score 0
	Joint damage absent		Score 0
	Joint damage present		Score 4

Rules were made for retrospectively checking, mapping and scoring of the ACR-EULAR criteria (eight domains) based on clinical items embedded in the existing primary care dataset. [a]Definition was not necessary. If in the study dataset no ankle or foot joint was involved (implying automatically joint involvement other than ankle, midfoot or first MTP1) score was set 0. [b]Was checked and scored without exactly knowing the time course of previous patient reported attacks. DECT: dual-energy computed tomography; MTP1, first metatarsophalangeal; VAS: visual analogue scale.

Table 2 Patient characteristics

Characteristic	MSU crystal-positive (n = 216)	MSU crystal-negative (n = 165)
Gender		
Male	193 (89.4)	92 (55.8)
Female	23 (10.6)	73 (44.2)
Age, mean (S.D.), years	59 (13)	56 (14)
Characteristics used for mapping		
Joint pattern		
Other joint	13 (6.0)	68 (41.2)
Ankle/midfoot	24 (11.1)	42 (25.5)
MTP1	179 (82.9)	55 (33.3)
Typical episode features		
None	5 (2.3)	11 (6.7)
One	49 (22.7)	51 (30.9)
Two	65 (30.1)	51 (30.9)
Three	97 (44.9)	52 (31.5)
Typical time course		
None	12 (5.6)	35 (21.2)
One episode	44 (20.4)	60 (36.4)
Recurrent	160 (74.1)	70 (42.4)
Tophus (clinical)		
Absent	189 (87.5)	165 (100.0)
Present	27 (12.5)	0 (0.0)
Serum urate		
<4 mg/dl	2 (0.9)	23 (14.0)
4–6 mg/dl	9 (4.2)	71 (43.3)
6–8 mg/dl	98 (45.4)	44 (26.8)
8–10 mg/dl	82 (38.0)	22 (13.4)
>10 mg/dl	25 (11.6)	4 (2.4)
SF analysis		
MSU positive	216 (100)	0 (0.0)
MSU negative	0 (0.0)	165 (100.0)

Values are given as n (%) unless otherwise indicated. MTP1, first metatarsophalangeal joint.

but did so during a later episode in the follow-up (recurrent attack). After at least 1 year follow-up 165 patients (43%) were defined as MSU crystal-negative. The patients who were MSU crystal-positive were more frequently male (89% *vs* 56%) and were slightly older (59 *vs* 56 years) than MSU crystal-negative patients. Tophus was present in 13% of the MSU crystal-positive patients. The first metatarsophalangeal joint (MTP1) was the joint currently involved in 56% of patients with identified MSU crystals and had ever been involved in 83% of them. Only 11 patients were taking urate-lowering therapy at the time of inclusion (6/216 of MSU crystal-positive patients, 5/166 of MSU crystal-negative patients).

MSU crystal-negative patients (n = 165) had the following diagnoses: OA (19 patients), calcium pyrophosphate deposition disease (14 patients), tested positive for CCP antibodies or RF or had progression to RA (12 patients), PsA (6 patients), post-streptococcal arthritis (5 patients), palindromic rheumatism (5 patients), arthritis secondary to IBD (4 patients), Lyme disease arthritis (3 patients), septic arthritis (3 patients), ReA (1 patient), no arthritis (12 patients), undifferentiated arthritis (81 patients).

Performance characteristics of the 2015 ACR-EULAR gout classification criteria (full and clinical-only version), and the 2010 Gout Diagnostic Decision Rule are shown in Table 3. The area under the receiver operating characteristic curve was highest for the 2015 ACR-EULAR full version (0.96), and comparably high (0.87) for the 2015 ACR-EULAR clinical-only version (not including the item SF analysis in the algorithm for all cases) and the 2010 diagnostic decision rule. Sensitivity and NPV were highest for the 2010 diagnostic decision rule, but specificity was lowest. Specificity and PPV were highest for the 2015 ACR-EULAR full version. Among the MSU crystal-negative group only three patients fulfilled both versions of the 2015 ACR-EULAR criteria (false positivity). When comparing predicted with observed probabilities (Fig. 1) there was good agreement for both versions of the ACR-EULAR criteria. This was also shown by non-significance of the Hosmer–Lemeshow test for the full version (P = 0.995; after excluding one outlier), as for the clinical-only version (P = 0.378).

Discussion

Testing of the 2015 ACR-EULAR gout classification criteria in additional external samples, particularly in settings (e.g. primary healthcare) from which individuals with gout are likely to be recruited for enrolment into trials or prospective epidemiological studies, is important for understanding its generalizability and feasibility in such settings [3, 4]. The present study is the first to examine the performance characteristics of the 2015 ACR-EULAR criteria in a primary healthcare setting.

In the studied Dutch primary care population of patients presenting with monoarthritis, both the full and clinical-only version of the 2015 ACR-EULAR gout classification criteria were shown to have a high discriminating value for MSU crystal confirmed gout. We found a very high specificity and PPV (the highest for the full version, in which presence and absence of MSU crystals was scored as 0 and −2, respectively), indicating that these criteria have an excellent performance in identifying the presence of gout in the primary care setting at the published threshold of 8. The specificity and PPV were even higher than those of a diagnostic decision rule for gout that was derived in the same dataset. At the threshold of 8, the criteria were relatively insensitive, and therefore not as good for excluding gout in this population (sensitivity only 0.68, leading to an NPV of maximum 0.70). Sensitivity, specificity PPV and NPV were all higher than those of the 1977 ARA Preliminary Criteria for the Classification of the Acute Arthritis of Primary Gout, which were also assessed in the current dataset in a prior study (0.80, 0.64, 0.80 and 0.65, respectively) [8].

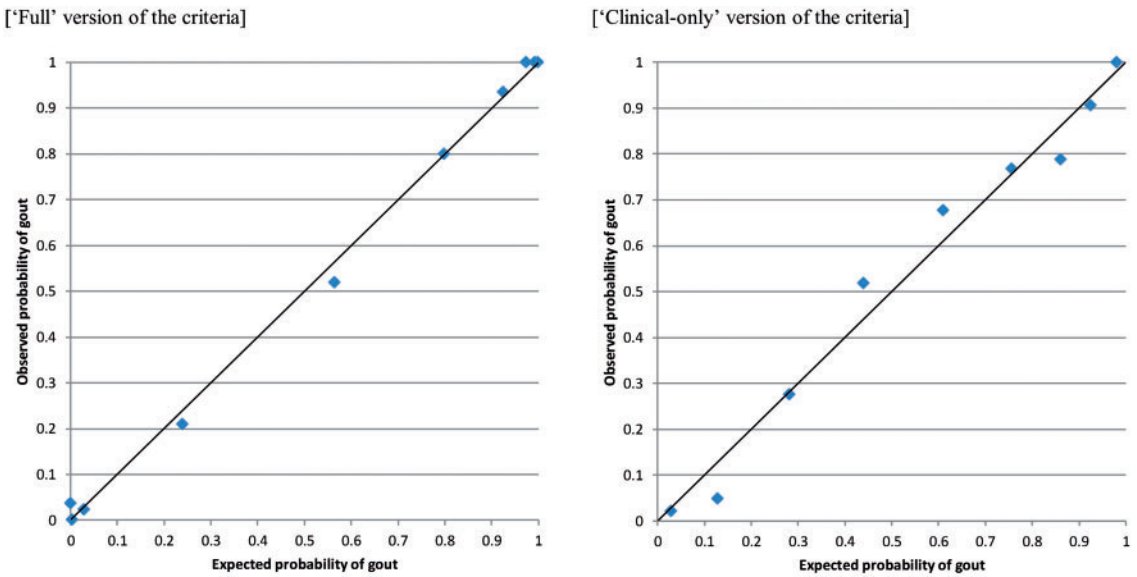
It is not immediately apparent why the 2015 ACR-EULAR criteria should have relatively low sensitivity in this sample. In this context several aspects need to be considered. Firstly, the unavailability of imaging items (scored 0 for all cases to indicate not done) could have

Table 3 Test performances

Criteria	AUC (95% CI)	Sensitivity	Specificity	PPV	NPV	LR +	LR −	Accuracy
2015 ACR-EULAR (full version)	0.96 (0.95, 0.98)	0.68	0.98	0.98	0.70	37.43	0.33	0.81
2015 ACR-EULAR (clinical-only version)	0.87 (0.83, 0.91)	0.68	0.84	0.85	0.67	4.32	0.38	0.75
2010 Gout Diagnostic Decision Rule	0.87 (0.84, 0.91)	0.91	0.71	0.80	0.86	3.14	0.12	0.82

Comparison of the diagnostic performance parameters of the full and clinical-only versions of the 2015 ACR-EULAR gout classification criteria and the 2010 Gout Diagnostic Decision Rule. Cut-point for classification of gout is eight or more for all criteria sets. AUC: area under the receiver operating characteristic curve.

Fig. 1 Calibration plots



Calibration plots for both versions of the ACR-EULAR gout classification criteria, showing (for each decile of the criteria score) the expected probability of gout by the observed probability of gout.

disadvantaged the sensitivity, as MSU deposition may have been detected by US or dual-energy computed tomography (score 4) in some cases (falsely negative according to the criteria). Secondly, it is very probable that the disease severity or disease activity of gout seen in this primary care study of patients presenting with monoarthritis only was lower (more risk of false negativity), compared with the SUGAR study, which also included patients with oligoarthritis or polyarthritis. The SUGAR study provided the main (secondary and tertiary care) test data for the international collaborative working group that developed the final 2015 ACR-EULAR criteria. MSU crystal-positive patients with flare recurrences or tophi were seen less in the present study compared with the SUGAR study (75% *vs* 90%, and 13% *vs* 34%, respectively), whereas patients with a serum urate (sUA) concentration lower than 8 mg/dl were seen more frequently (51% *vs* 26%) [5, 7]. In contrast, the proportion of non-gout patients with sUA lower than 8 mg/dl) was similar in both studies (84% *vs* 76%).

Besides the probability of low disease severity or disease activity, which might have led towards less severe hyperuricaemia, there are at least two reasons for the relatively low sUA levels observed in this primary care study population. Firstly, sUA was measured during an acute episode, whereas the 2015 ACR-EULAR criteria recommend that it should be ideally measured (if practicable) during an intercritical period because of the possibility that spuriously lowered sUA levels may occur during an acute episode. However, the evidence that sUA is lower during an acute episode of gout if compared with an intercritical periode is weak or contradictory, despite a common belief that this is the case [9, 10]. Secondly the 2015 ACR-EULAR criteria specification that the highest ever sUA needs to be used (and at a time when a patient is not taking urate lowering treatment) [3, 4] will inevitably lead to higher sUA values than if a single value (often from a current episode) is used. This was seen in the SUGAR study (mean current sUA 7.90 mg/dl; mean highest

recorded sUA without urate lowering therapy 9.58 mg/dl). However, mean current sUA in the present study was higher if compared with the SUGAR study (8.24 mg/dl), which is probably a representative value from more frequent first episodes in primary care.

The lower sUA levels in the MSU crystal-positive patients will have a significant effect on the 2015 ACR-EULAR criteria scores, since the item sUA level is level dependent (the higher the level, the higher the score), and is weighted quite strongly (maximum score of 4). If the MSU crystal-positive patients in this sample would have one higher sUA category than was observed, then the sensitivity of the 2015 ACR-EULAR criteria increases to 89% (data not shown).

The major strength and uniqueness of this study is that the MSU crystal status of each patient was confirmed by SF microscopy by an experienced observer. MSU crystal negativity was additionally defined by the presence of an established other rheumatic disease or by a period of at least 1 year free of recurrent arthritis, if no specific diagnosis could be made. Although after this misclassification risks still can exist (e.g. no detectable MSU crystals at initial or, in case, again at recurrent presentation), there are no other studies in a primary care setting that has confirmed or excluded the presence of MSU crystals in this rigorous way.

The main limitation of this study regards the fact that the data were collected previous to the development of the ACR-EULAR criteria. The data did not exactly follow the definitions for the items in the criteria and therefore needed to be mapped. This was unavoidable since the definitions were not available at the time of data collection, and the criteria were applied retrospectively. Although a prospective study design would have met this limitation, it was not currently feasible to engage in such a large undertaking, and should be in the scope of future research. Nonetheless, we consider the current study as an important first attempt to externally validate the 2015 ACR-EULAR criteria. The criteria 'cannot bear touch or pressure to affected joint' (representing a patient reported severe joint pain), and 'great difficulty with walking or inability to use affected joint' were mapped using a threshold on a patient reported visual analogue scale. This was not how the 2015 ACR-EULAR criteria define this, but is a fair approximation, though our 50 mm threshold choice was arbitrary. However, this choice for pain severity may actually be a reliable and sensitive approach, considering that in the SUGAR study median pain level (categorical scale 0–10) during a current episode was 8 (interquartile range = 7–10) and proportion of patients with a level $\geqslant 7$ was 79% [5].

The limitation of the unavailability of imaging has been already discussed, recognizing that advanced imaging techniques such as ultrasound or dual energy CT will be less readily available in primary care, although there might be a chance for easy to use point-of-care US devices, and radiography is readily available. The large group of patients (21%) with undifferentiated arthritis (risk of falsely negative SF analysis) compared with the SUGAR study (6%) may raise concerns, though patients remained free of recurrent attacks (for typical gout episodes) for at least 12 months. In addition (self-limiting), undifferentiated arthritis in primary care might be also representative for lower disease activity of rheumatic diseases other than gout. The presented diagnostic performance parameters apply to patients with monoarthritis, and may differ if also patients were included with oligoarthritis or polyarthritis. It can be expected that those kinds of patients are rare in the primary care setting. Finally, the 2015 ACR-EULAR classification criteria were compared with the 2010 Gout Diagnostic Decision Rule, which was not developed for classifying, but rather for diagnosing, gout (and finally for guiding the physician user for further management), using patient characteristics that are not *per se* (acute or chronic) disease characteristics. In contrast, criteria like the 2015 ACR-EULAR criteria are not intended for use in making a probable gout diagnosis in a specific person in daily medical practice [3, 4]. Although diagnostic and classification criteria could potentially be the same for gout (in the case of MSU crystal positivity), classification is about testing the presence or absence of a disease, principally irrespectively of the patients' context [11, 12]. Hence, one could have expected in the current study differences in diagnostic performance between the diagnostic rule and the ACR-EULAR (classification) criteria.

Despite these potentially important issues, the 2015 ACR-EULAR gout classification criteria appear to have very high specificity in a primary care population of patients presenting with monoarthritis. The high PPV suggests that these criteria could be used to enrol patients suspected of having gout into clinical trials that recruit directly from primary care. This is a key requirement for classification criteria for gout. Further prospective studies using the criteria elements as actually defined rather than mapped surrogates are required to confirm these findings, and to determine whether the sensitivity of the criteria would be better, for example, by checking cases for the highest available sUA (ever) measured during an intercritical phase, as is recommended [3, 4], or considering modification of the sUA categories, keeping in mind a lesser disease severity or activity of gout in primary care patients.

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Supplementary data

Supplementary data are available at *Rheumatology* Online.

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