The limited validity of the criteria of the American College of Rheumatology for classifying gout patients in primary care

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In order to classify gout without identification of monosodium urate (MSU) crystals, the American College of Rheumatism (ACR) formulated criteria in 1977.[1] Of 11 criteria, 6 or more have to be present to classify patients as having gout. The criteria were not developed with reference to MSU crystals, nor were they tested properly afterwards against this gold standard.[1,2,3] But, as they are widely used, and cited, testing their validity is critical to our ability to understand and treat gout.[4]

Many gout studies include patients with 'self-reported gout', if patients fulfill the ACR criteria. Most self-reported diagnoses of gout will originate from a diagnosis made by family physicians (FPs), as most patients presenting acute gout are managed by them.[2,5] That makes the primary care setting particularly relevant to test the ACR criteria.

We designed a prospective study in a Dutch primary care population (~200,000 people) to estimate the validity of the ACR criteria (patient recruitment 2004-2006). We used identified MSU crystals as reference test, as recommended by the European League Against Rheumatism.[2] Recruited patients, presenting a mono-arthritis, were included if FPs suspected gout in them. Within 24 hours an experienced rheumatologist assessed the ACR criteria, and analyzed aspirated synovial fluid for MSU crystals in all patients – with and without a FPs' diagnosis of gout. If MSU crystals could not be identified, patients were assessed for other joint diseases. If MSU crystals were identified during follow-up, the patient was re-classified as having 'gout', with an initial false-negative test. To calculate test characteristics, 2x2 tables were used.

Table 1. The 2x2 table with '6 or more positive ACR-criteria' as index test and MSU-crystals, identified in the synovial fluid of the affected joint, as reference test, in 328 patients with a gout diagnosis according to the FP.

	MSU-crystals identified	No MSU-crystals identified	
6 or more positive ACR-criteria	168	43	211
Less than 6 positive ACR-criteria	41	76	117
	209	119	328

Of 381 patients presenting a mono-arthritis, 159 (42%) had their MTP1 joint affected, 222 (58%) an other joint. In 328 (86%) patients FPs made a gout diagnosis; mean age 58.0 yr (SD:13.5); male 261 (80%); MSU crystals identified in 209 (64%) - in 202 at the initial investigation and in 7 during follow-up. In 53 patients FPs suspected no gout - MSU crystals in 7 (13%).

The ACR criteria showed a limited validity: sensitivity 0.80, specificity 0.64, positive predictive value 0.80, and negative predictive value 0.65 (table 1). After modifying the cut-off point of 6 or more positive items test characteristics did not substantially improve (table 2).

Table 2. The test characteristics of different numbers of positive ACR-criteria (index tests) using the identification of MSU-crystals as reference test in 328 patients with a gout diagnosis according to the FP.

Number of positive criteria	Sensitivity	Specificity	Positive predictive value	Negative predictive value	Overall fraction correct
4 or more	1.00 (208/209)	0.24 (28/119)	0.70 (28/119)	0.97 (28/29)	0.72 (236/328)
5 or more	0.95 (198/209)	0.35 (41/119)	0.72 (198/276)	0.79 (41/52)	0.73 (239/328)
6 or more	**0.80 (168/209)**	**0.64 (76/119)**	**0.80 (168/211)**	**0.65 (76/117)**	**0.74 (244/328)**
7 or more	0.57 (120/209)	0.82 (98/119)	0.85 (120/141)	0.52 (98/187)	0.67 (218/328)
8 or more	0.26 (55/209)	0.93 (111/119)	0.87 (55/63)	0.42 (111/265)	0.51 (166/328)
9 or more	0.07 (15/209)	0.99 (118/119)	0.94 (15/16)	0.38 (118/312)	0.41 (133/328)

Malik et al. tested recently the ACR-criteria, as we did, against the gold standard, reporting comparable, moderate test characteristics (sensitivity 0.70, specificity 0.78). [3] However, important differences exist between our both studies. We studied patients presenting gouty joint symptoms to FPs, while Malik studied patients selected in a rheumatology clinic "only because they had had synovial fluid aspirated and analyzed at some time". In our study most patients presented a MTP1 arthritis and occasionally a knee arthritis (as can be expected in primary care), but in Maliks' study more than 75% of the patients had an aspiration from the knee and only a few from MTP joints.

Our findings pertain to patients with mono-articular gout according to FPs. This reflects the primary care setting, where most cases of gout are mono-articular and occasionally oligo- or polyarticular.[5]

Aspirated fluid was sensitively searched for crystals, and detected crystals were specifically identified by rheumatologists with experience in synovial fluid analysis. The proportion of patients at risk for a false negative test was low in our study.

We tested the ACR criteria in a relevant population representative for patients having gout diagnosed by doctors without joint fluid investigation. Additionally to Maliks' study,[3] our findings show the limited validity of the ACR criteria, and support the empirical evidence[4] of interpreting with caution the estimates of incidence and prevalence,[6] causal associations,[7,8] and effects of interventions,[9] in studies which used the ACR criteria for patient inclusion.

Conflict of interest statement
We declare that we have no conflict of interest.

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