Diagnostic Value of Clinical, Laboratory, and Imaging Findings in Patients with a Clinical Suspicion of Gout: a Systematic Literature Review

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ABSTRACT. ***Objective***. To analyze the diagnostic utility of clinical, laboratory, and imaging items for gout.

Methods. A systematic literature search was performed in MEDLINE, EMBASE, and The Cochrane Library; and a manual search of abstracts from the 2010/2011 meetings of the American College of Rheumatology (ACR) and the European League Against Rheumatism, as well as the reference lists of retrieved papers. Studies were included if they evaluated the diagnostic utility of clinical, laboratory, or imaging features or criteria for the diagnosis or classification of gout in adult patients. Two independent reviewers selected papers, extracted the data, and assessed the risk of bias.

Results. Nineteen studies were included in the review; 4 used the identification of monosodium urate (MSU) crystals as the reference standard (RS) and the rest used expert opinion or the ACR preliminary criteria. Most features were evaluated in a single study. Evidence for diagnostic utility, using MSU crystals as RS, of over 50 individual clinical, laboratory, and radiographic features was retrieved. Most items showed a positive likelihood ratio (LR+) < 3, except for the following: response of arthritis to colchicine (LR+ 4.3); presence of tophi on physical examination (LR+ 15.6–30.9); identification of the double-contour sign in ultrasound (US) (LR+ 13.6); and detection of urate deposits by dual-energy computed tomography (DECT) (LR+ 9.5).

Conclusion. Individual clinical features show low diagnostic utility, with the exception of tophi and response to colchicine. Some US and DECT findings show better performance than most clinical features. (J Rheumatol Suppl. 2014 Sept; 92:3–8; doi:10.3899/jrheum.140456)

Key Indexing Terms:
GOUT MSU CRYSTALS HYPERURICEMIA DIAGNOSIS SYSTEMATIC REVIEW

Gout is caused by the deposit of monosodium urate (MSU) crystals in and around joints, resulting in bouts of acute arthritis separated by asymptomatic intercritical periods. Once diagnosed, gout patients frequently undertake lifelong urate-lowering therapy; therefore, a firm diagnosis of gout is essential in planning appropriate patient care. Current recommendations support the use of MSU crystal identification to establish a definite diagnosis of gout[1,2]. However, microscopic analysis of an aspirated synovial fluid (SF) sample is not a widespread procedure in clinics[3], especially in primary care, where gout is most often diagnosed and managed. Some recommendations — based on expert opinion and a critical appraisal of the literature — suggest that "typical" presentations (such as recurrent podagra with hyperuricemia) can be reasonably specific, forgoing the need for confirmation through crystal identification[1,2]. The possibility of establishing an accurate gout diagnosis without joint aspiration and microscopic analysis is an attractive scenario.

This article is part of the 3e (Evidence, Expertise, Exchange) Initiative on Diagnosis and Management of Gout[4]. The objective of the current report was to systematically review the literature on 1 of 10 selected questions, as an evidence base for generating recommendations:

> Under which circumstances can a diagnosis of gout be made on clinical grounds with or without laboratory tests or imaging, and when is identification of crystals necessary?

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MATERIALS AND METHODS

This systematic literature review (SLR) was performed according to the guidelines of the Cochrane Handbook for Diagnostic Tests Reviews[5].

Rephrasing the question using the PICOT formula. The original question was rephrased to make it correspond to the PICOT concept as applied to diagnostic test reviews (Population, Index Test, Reference Standard, Outcome, Study Type). In this context we defined (1) population (P) as consisting of adult patients with a clinical suspicion of gout; (2) index test (I) as a clinical, laboratory, or imaging finding — or set of classification or diagnostic criteria; (3) reference standard (C) as MSU crystal identification, expert opinion, or classification criteria for gout; (4) outcomes (O) as sensitivity, specificity, likelihood ratios (LR), or area under the curve (AUC, or these as calculated from published data); and (5) study type (T) as any type that could answer the diagnostic question.

Systematic literature search. A systematic literature search was carried out in PubMed (to October 2011), EMBASE (1974 to October 20, 2011), and The Cochrane Library. The search strategy combined a general 3e Initiative strategy for gout and the McMaster Diagnostic Filter maximized for sensitivity (for a complete search strategy see Appendixes 1–3, available from http:/www.3egout.com). We performed a manual search of abstracts from the last 2 European League Against Rheumatism (EULAR) and American College of Rheumatology (ACR) meetings (2010–2011) and of the reference list of all relevant papers and review articles.

Study selection, data extraction, and risk of bias assessment. Two reviewers (FS, MA) independently screened titles and abstracts, then reviewed potentially relevant articles in full text for inclusion, and performed the data extraction and risk assessment of the selected studies. If the 2 reviewers disagreed, a consensus was sought; if unattainable, a third reviewer performed as arbiter (LC). Articles that did not fulfill all inclusion criteria or had insufficient data for analysis were excluded. Included articles had to be available in English or in a language that could be read by one of the 3e Initiative Multinational Bibliographic team (Dutch, French, German, Spanish). Articles published in languages other than English that did not have an English abstract were excluded. Studies evaluating the reliability of crystal identification or other findings in the SF were excluded. Only studies available as full articles or as a full trial report were included.

Ad hoc standardized forms were piloted and used for data extraction. Risk of bias assessment was performed through the Cochrane tool for diagnostic studies[6] adapted and piloted to our systematic search.

Data analysis. We retrieved or calculated sensitivity, specificity, positive LR (LR+) and negative LR (LR–), or AUC for each individual feature, and estimated the 95% confidence intervals (95% CI). Analysis was performed using RevMan 5.1 (Copenhagen: The Nordic Cochrane Center, The Cochrane Collaboration, 2011). Given the clinical heterogeneity of the retrieved results, no metaanalysis was performed. There are no well-established cutoff points at which a given diagnostic test is considered adequate. For the purposes of this review, we considered items with a LR+ < 3 or a LR- > 0.2 as having a poor diagnostic utility.

RESULTS

The search strategy retrieved 5558 articles, of which 48 were selected after title and abstract screening; an additional 6 articles were identified through the manual reference search (Figure 1). Out of the 54 articles, 34 were excluded (see Appendix 4, available online from http:/www.3egout.com); the remaining 20 articles (reporting 19 studies) fulfilled all inclusion criteria and data were extracted from them. Eight meeting abstracts were selected, but all were excluded after detailed review.

Included studies[7-11,12-16,17-21,22-26]. Details on the population and index tests of the 19 included studies are available in Table 1 (reference standard is MSU crystals) and Appendixes 5 and 6 available online (other reference standards also available) from http:/www.3egout.com. Overall, included studies were considered of a low[11], unclear[14,16], or high[7,8,9,10,13,15,17-21,21-26] risk of bias (see Appendix 5, available from http:/www.3egout.com). Four studies (5 articles) used MSU crystal identification as their reference standard[11,14,16,26] (currently the best available reference standard). Of these, 2 studies evaluated clinical, laboratory, and radiographic features, along with the performance of the older sets of classification criteria (Rome, New York, and preliminary ACR criteria[24]), 1 assessed ultrasound (US) findings and the last evaluated the use of dual-energy computer tomography (DECT) scanning. The remaining 15 studies used expert opinion (n = 14) or ACR preliminary classification criteria (n = 1) as reference standard. Of these, 4 studies evaluated clinical and laboratory findings, 3 evaluated radiographic features, 7 US findings, 2 DECT, 1 technetium-99m-anti-CD3 scintigraphy, and 1 wrist arthrogram.

MSU as reference standard[11,14,16,26]. Clinical, laboratory, and radiographic features were assessed in 2 studies: the first[11,12] recruited 381 patients with acute monoarthritis who presented to primary care, the second[16] reviewed 82 patients in whom a search for MSU crystals was performed from a SF sample in a single rheumatology department. Table 2 summarizes the performance of selected individual clinical features for the diagnosis of gout in these studies. Except for response to colchicine and presence of tophi, all other evaluated features presented a LR+ < 3 and LR– > 0.20 (male sex, maximum inflammation within hours, self-reported attacks, monoarthritis, arthritis in the same joint, family history of gout, recent joint trauma or surgery, use of medication such as diuretics, antiplatelet drugs, antihypertensive or cardiovascular drugs, comorbidities such as diabetes, hypertension, cardiovascular disease, renal stones, alcohol intake (overall, beer, wine, or liquor intake), foot/ankle involvement, lower leg involvement, redness over joint, body mass index [(BMI) > 25 kg/m^2, BMI > 30 kg/m^2)], systolic blood pressure > 140 mmHg, diastolic blood pressure > 90 mmHg). Hyperuricemia was also assessed using several definitions (Table 3). It is noteworthy that serum uric acid (sUA) was measured during the acute episode in the first study[11] while the timing is unknown in the second study[16], as it has been suggested that sUA drops during an acute inflammatory episode[27,28]. Laboratory data other than hyperuricemia [estimated glomerular filtration rate (eGFR) < 60 ml/min, eGFR < 90 ml/min, creatinine > 1.19 mg/dl, erythrocyte sedimentation rate > 20 mm in men and > 30 mm in women, C-reactive protein > 1 mg/dl, negative SF culture) have all shown a poor diagnostic utility.

In a single study[16] radiographic features (asymmetric swelling and subcortical cysts without erosions) have shown

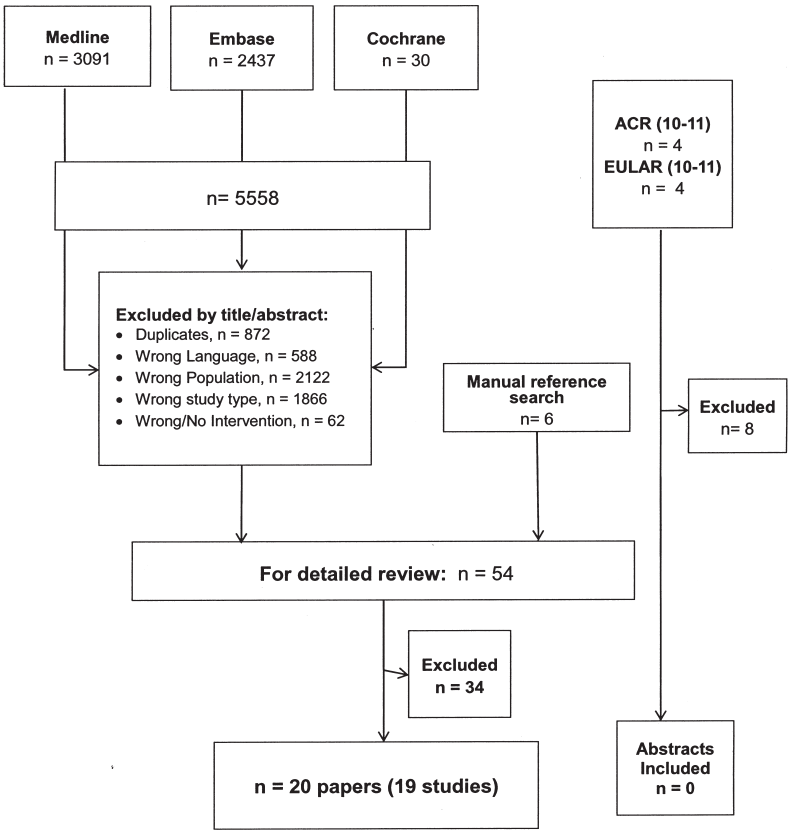

Figure 1. The literature search procedure and included studies.

Table 1. Characteristics of included studies using identification of MSU crystals as reference standard.

Study	Population	Index Test
Glazebrook, 2011[26]	31 patients (12 gout/19 other). Single-gated (patients who underwent a DECT with gout protocol and SF analysis). Recruited from radiology, rheumatology or orthopaedic clinic. Retrospective	DECT
Janssens, 2010[11,12]	381 patients (216 gout/165 other). Single-gated (monoarthritis). Recruited from GP clinics. Prospective	Clinical, laboratory, and radiographic features. Diagnostic/Classification criteria
Lai, 2011[14]	80 patients (34 gout/46 other). Single-gated (mono or oligoarthritis who underwent SF aspiration and analysis). Recruited from a rheumatology division. Retrospective	US (of symptomatic joints)
Malik, 2009[16]	82 patients (30 gout/52 other). Single-gated (patients who underwent SF analysis). Recruited from a hospital-based rheumatology clinic. Retrospective	Clinical, laboratory radiographic features. Classification criteria

Single-gated: A single set of criteria for study entry; SF: snyovial fluid; US: ultrasound; DECT: dual-energy computer tomography; GP: general practitioner.

a low sensitivity (0.13 and 0.19, respectively) but high specificity (0.94 for both). This is in keeping with the natural history of gout in which radiographic changes are thought to appear in long-standing, untreated (or under-treated) gout. US features were evaluated in a single study using MSU crystals as reference standard[14]. The study includes 104 symptomatic joints with acute or subacute mono or oligoarthritis that have undergone US and joint aspiration with crystal analysis in a single center's rheumatology clinics. Among other assessments, the study evaluated the presence of the double-contour sign (a hyperechoic deposition on the surface of the hyaline cartilage forming an irregular band paralleling the bone contour) and tophi (defined as a hyperechoic area with a hypoechoic rim). Results are summarized in Table 4. The single study evaluating use of DECT to detect joint urate deposits[26] retrospec-

Table 2. Diagnostic utility of individual clinical features for gout diagnosis (MSU identification as reference standard).

	Reference (n)	Sensitivity (95% CI)	Specificity (95% CI)	LR+	LR–
Tophus	J (328)	0.13 (0.09, 0.18)	1.00 (0.97, 1.00)	30.88	0.87
	M (69)	0.37 (0.19, 0.58)	0.98 (0.87, 1.00)	15.56	0.65
Response to colchicine	M (31)	0.67 (0.41, 0.87)	0.85 (0.55, 0.98)	4.33	0.39
History of 1st MTP painful or swollen	M (81)	0.83 (0.65, 0.94)	0.69 (0.54, 0.81)	2.66	0.24
Unilateral podagra	M (81)	0.77 (0.58, 0.90)	0.71 (0.56, 0.83)	2.61	0.33
1st MTP involvement	J (328)	0.57 (0.50, 0.64)	0.71 (0.62, 0.79)	1.95	0.60
Unilateral tarsitis	M (79)	0.48 (0.29, 0.67)	0.78 (0.64, 0.88)	2.19	0.66
Foot/ankle involvement	J (328)	0.77 (0.71, 0.83)	0.37 (0.28, 0.46)	1.22	0.62
Lower leg involvement	J (328)	0.86 (0.80, 0.90)	0.21 (0.14, 0.29)	1.08	0.68
Maximum inflammation in 1 day	M (78)	0.82 (0.63, 0.94)	0.60 (0.45, 0.74)	2.05	0.30
	J (328)	0.79 (0.73, 0.85)	0.24 (0.17, 0.33)	1.05	0.84
Onset at night	M (65)	0.90 (0.70, 0.99)	0.48 (0.32, 0.63)	1.73	0.20
Male sex	J (328)	0.89 (0.84, 0.93)	0.38 (0.29, 0.47)	1.44	0.28
Medication: diuretics	J (328)	0.31 (0.25, 0.38)	0.82 (0.73, 0.88)	1.68	0.85
Com: CV disease	J (328)	0.31 (0.24, 0.37)	0.86 (0.78, 0.91)	2.14	0.81
Com: renal stones	J (328)	0.09 (0.06, 0.14)	0.94 (0.88, 0.98)	1.55	0.97
Alcohol, any	J (327)	0.63 (0.56, 0.70)	0.45 (0.36, 0.54)	1.15	0.82

MSU: monosodium urate; J: Janssens, et al[11]; M: Malik, et al[16]; LR+: positive likelihood ratio; LR–: negative likelihood ratio; MTP: metatarsophalangeal joint; max: maximum; Com: comorbidities: CV: cardiovascular.

Table 3. Diagnostic utility of hyperuricemia for gout diagnosis (MSU identification as reference standard).

	Reference (n)	Sensitivity (95% CI)	Specificity (95% CI)	LR+	LR–
Hyperuricemia*	M (51)	0.89 (0.72, 0.98)	0.61 (0.39, 0.80)	2.28	0.18
sUA > 7.06 mg/dl in men/ > 5.72 mg/dl in women	J (327)	0.77 (0.71, 0.83)	0.68 (0.59, 0.76)	2.39	0.34
sUA > 5.88 mg/dl	J (327)	0.95 (0.91, 0.98)	0.53 (0.44, 0.63)	2.04	0.09

*No further definition of hyperuricemia provided. MSU: monosodium urate; J: Janssens, et al[11]; M: Malik, et al[16]; sUA: serum uric acid, LR+: positive likelihood ratio, LR–: negative likelihood ratio.

Table 4. Diagnostic utility of US findings for gout diagnosis (MSU identification as reference standard)[14].

	Sensitivity (95% CI)	Specificity (95% CI)	LR+	LR–
Double contour	0.37 (0.22, 0.54)	0.97 (0.86, 1.00)	13.63	0.65
Tophi	0.12	1.00	ND	0.88
Punctiform deposits in synovial membrane	0.77 (0.63, 0.87)	0.65 (0.51, 0.78)	2.22	0.35
Hyperechoic spots in synovial fluid	0.26 (0.14, 0.40)	0.82 (0.69, 0.91)	1.42	0.91

MSU: monosodium urate; LR+: positive likelihood ratio, LR–: negative likelihood ratio, ND: no data.

tively evaluated 31 patients who underwent DECT with a gout protocol and crystal analysis in SF sample in a single hospital; use of DECT showed a high LR+ (9.5) and a low LR– (0.05).

The performance of older classification criteria has also been compared to MSU crystal identification. The ACR preliminary classification criteria were evaluated in 2 studies[12,16] with LR+ 2.22–3.33 and LR– 0.31–0.38. One study[16] also evaluated an adaptation of the Rome criteria (LR+ 6.01, LR– 0.37) and the New York criteria (LR+ 4.12, LR– 0.36). Because they were compared to MSU identification, we excluded all features referring to crystal identification in the criteria for our analysis.

A new rule for the diagnosis of acute gouty arthritis in primary care without SF analysis was developed using results of a prior study[11]. It consists of a weighted score of 7 individual features — male sex, self-reported gout attack, 1st metatarsophalangeal (MTP) involvement, maximum inflammation appearing within 1 day, redness over the joint, hypertension or another cardiovascular disease as comorbidity, and sUA > 5.88 mg/dl — giving a total score ranging from 0 to 13. Suggested cutoff points for gout diagnosis:

total score ≤ 4 = unlikely; ≥ 8 = likely; 5–7 = indeterminate. The LR– of total score ≤ 4 = 0.01, and the LR+ of total score ≥ 8 = 2.66; overall AUC = 0.85.

Other reference standards. Several clinical, laboratory, and imaging features assessed in previous studies were also compared to other reference standards (expert opinion or the ACR classification criteria); for details of these studies see Appendix 6 (available online from http:/www.3egout.com). Overall, the individual clinical findings tended to show a markedly better diagnostic utility (higher LR+ and lower LR–) when expert opinion is used as the reference standard. However, risk of bias in these studies is high because the risk for circularity is increased [incorporating the index test (individual clinical or laboratory features) into the reference standard (expert opinion)]. A new diagnostic rule (clinical gout diagnosis) has been tested in Mexican patients with gout, rheumatoid arthritis, spondyloarthritis, or osteoarthritis[21]. Eight clinical and laboratory features — based on the original ACR classification criteria — were qualified as present or absent; for a diagnosis of gout, 4 or more items must be present. In this population diagnostic utility was considered to be very high (LR+ 22.39, LR– 0.03), although these results should be interpreted with caution because they have not been compared against MSU crystal identification as reference standard.

DISCUSSION

Recommendations and expert opinion highlight the need for an MSU crystal investigation and identification in patients with a clinical suspicion of gout in order to establish a definite diagnosis of gout. However, there have been recurrent efforts to find alternative, noninvasive methods to establish diagnosis with sufficient accuracy. This has recently led to the development of 2 sets of diagnostic criteria and to the assessment of advanced imaging techniques (US and DECT). Our present systematic literature review (SLR) provides a comprehensive overview of current evidence on the performance of individual and combined diagnostic tests, with the aim of providing tools that support a clinician's decision on when to forgo joint aspiration and MSU crystal identification.

Most individual features have a low diagnostic utility as standalone diagnostic tools. The higher the LR+, the greater the increase in post-test odds that the feature is present. Conversely, the lower the LR–, the greater the decrease in post-test odds that the feature is absent. Although over 50 individual clinical and laboratory features have been assessed, only presence of tophi and previous response of acute arthritis episode to colchicine showed LR+ > 3. Features systematically used as diagnostic aids such as podagra/1st MTP involvement have shown poor diagnostic accuracy. Among the evaluated laboratory features, absence of hyperuricemia has shown a marked LR–, suggesting that gout is unlikely in the absence of hyperuricemia. Some US signs (presence of double-contour sign or tophi) and DECT features (detection of urate deposits) have shown a markedly better performance than clinical features. Despite high face validity, the diagnostic performance of the diagnostic rule for acute gout arthritis in primary care[11] has shown little improvement over individual items for the diagnosis of gout. The performance of the clinical gout diagnosis criteria[21] seems impressive, but the choice of non-gouty patients as those with an alternative established rheumatic disease, the particular epidemiology of gout and hospital referrals in Mexico, and the risk of circularity all suggest that these criteria need to be tested in further settings before their diagnostic performance can be adequately established.

A previous SLR[1] and a recently updated[2] literature search have explored the diagnosis of gout. Differences in methodology between previous SLR and ours resulted in the inclusion of different studies. Although the original search was performed in a wide variety of databases, the most recent literature update (February 2005–February 2011) was performed solely in PubMed. Our search incorporated 2 further databases (EMBASE and Cochrane Library); moreover, one included study was retrieved solely through EMBASE, using MSU as reference standard[14]. On the other hand, we included only primary diagnostic studies, excluding community studies, making our results directly relevant for patients with a clinical suspicion of gout. Our search also included assessment of advanced imaging techniques — such as US and DECT — and of classification/diagnostic criteria not included in prior attempts. But perhaps the most remarkable difference is the separation of studies by reference standards. The use of expert opinion as a reference standard incorporates an unquestionable risk of circularity, especially when clinical features or operator-dependent features are considered. Although the identification of MSU crystals is the best available reference standard, it is still far from perfect. When crystals are identified, gout is unequivocally present, but a different form of arthritis (i.e., septic arthritis) can coexist and cause the current symptoms[29]. Conversely, several factors can make identification of MSU crystals difficult in patients with gout[30], not the least of which is analyst training. Noteworthy efforts were undertaken in the largest study to confirm the validity of not finding MSU crystals initially (1-year followup and repeat SF analysis if a new bout of arthritis appeared in all patients with arthritis of unknown origin), thereby reducing the risk of false-negative findings on the first SF test.

In conclusion, evidence does not support the use of most individual clinical, laboratory, or radiographic features for establishing diagnosis of gout. Using a combination of features in the form of diagnostic rules or classification criteria could improve diagnostic yield, but current efforts have either not shown a significant increase in LR+ or need

further validation. Both US and DECT have shown a markedly better performance than clinical items and may have a potential role in establishing a gout diagnosis accurately; further testing should be encouraged.

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