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Article *in* Rheumatology International · April 2019

DOI: 10.1007/s00296-018-4220-0

Rheumatology International
https://doi.org/10.1007/s00296-018-4220-0

Rheumatology INTERNATIONAL

IMAGING

Reliability of OMERACT ultrasound elementary lesions in gout: results from a multicenter exercise

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Received: 6 November 2018 / Accepted: 1 December 2018

Abstract

The aim of this study was to evaluate the reliability of the outcome measures in rheumatology (OMERACT) definitions for ultrasound (US) elementary lesions in gout through an image reading exercise. Images from patients with gout (static images and videos) were collected. As an initial step, we carried out a image reading exercise within the experts of the Pan-American League of Associations for Rheumatology (PANLAR) US Study Group ($n=16$). The following step consisted in a web-based exercise with the participation of larger number of sonographers ($n=63$) from different centers. Images were rated evaluating the presence/absence of any US elementary lesion. Inter- and intra-reader reliabilities were analyzed using kappa coefficients. Participants were stratified according to their level of experience. In the first exercise, inter-reader kappa values were 0.45 for aggregates, 0.57 for tophus, 0.69 for erosions, and 0.90 for double contour (DC). Intra-reader kappa values were 0.86, 0.76, 0.80, and 0.90, respectively. The web-based exercise showed inter-reader kappa values for aggregates, tophus, erosions, and DC of 0.42, 0.49, 0.69, and 0.79, respectively. The intra-reader kappa values were 0.62, 0.69, 0.77, and 0.85, respectively. Reliability was not influenced by the sonographer's level of experience. The reliability of the new OMERACT US definitions for elementary lesions in gout ranged from moderate to excellent, depending on the type of lesion.

Keywords Gout · Ultrasound · Elementary lesions · Reliability

Introduction

Gout is an inflammatory disorder characterized by hyperuricemia and the deposition of monosodium urate (MSU) crystals, resulting in episodic gout flares, gouty arthropathy, and tophi formation [1]. It is one of the most prevalent

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Published online: 11 December 2018

inflammatory arthropathies in general population and is also associated with important comorbidities such as higher cardiovascular risk and renal impairment [2, 3].

The gold standard for the diagnosis of gout is the microscopic evaluation of the synovial fluid aspirate, which reveals the presence of negative birefringent needle-shaped MSU crystal under compensated polarize microscopy [4]. The identification of MSU crystals is not always possible due to several factors: difficulty of joint aspiration in small joints, the presence of small amount of fluid, deposition of crystals within tendons. Besides, synovial fluid aspiration may not reveal MSU crystals in up to 25% of patients with gout [5]. Given the aforementioned limitations, synovial aspirations are performed in a small number of patients. In cases of non-crystal proven gout in the joint aspirate, the clinical, radiographic, and laboratory assessment may be helpful in making the diagnosis. However, during an acute gout attack, the serum uric acid levels can be within the normal limits, and not all patients with hyperuricemia develop gout [6].

Over the last years, musculoskeletal ultrasound (US) has been progressively incorporated into the rheumatology clinical practice as a valuable tool to optimize the diagnosis and management of patients with rheumatic and musculoskeletal diseases [7].

The 2015 ACR/EULAR Gout Classification Criteria combine clinical, laboratory, and imaging domains [8]. Interestingly, these criteria highlight the role of US as a new tool to demonstrate the presence of MSU crystals. In fact, research work of the last decade provides a body of evidence supporting US for the diagnostic evaluation of patients with gout [9].

Although different US definitions for gout have been published, most of them result from single-center investigations with a large heterogeneity and variable US lesions, and there is no general consensus about the lesions that should be identified in patients with gout [10].

Recently, the OMERACT Gout US Task Force has developed a set of consensus-based definitions for elementary US lesions in gout as well as tested their reliability in still images and patients. These include the definition of four elementary lesions: tophus, double contour (DC), aggregates, and erosions [11, 12].

The increasing use of US in the daily practice by rheumatologists and the design of future research studies and clinical trials in gout make it necessary to test the performance of the new elementary OMERACT US definitions for gout among different groups of sonographers. The aim of this study was to test the reliability of these definitions through an image reading exercise in a large number of sonographers from Latin America.

Materials and methods

Study design

We designed a cross-sectional study based on the reading of images (static and dynamic) of patients with gout to evaluate the intra- and inter-reader reliabilities of the OMERACT US definitions for gout. These definitions describe four elementary lesions: *tophus*: a circumscribed, inhomogeneous, hyperechoic, and/or hypoechoic aggregation (which may or may not generate posterior acoustic shadow), which may be surrounded by a small anechoic rim; *aggregates*: heterogeneous hyperechoic foci that maintain their high degree of reflectivity, even when the gain setting is minimized or the insonation angle is changed and which occasionally may generate posterior acoustic shadow; *double contour*: abnormal hyperechoic band over the superficial margin of the articular hyaline cartilage, independent of the angle of insonation and which may be either irregular or regular, continuous or intermittent and can be distinguished from the cartilage interface sign; *erosion*: an intra- and/or extra-articular discontinuity of the bone surface (visible in two perpendicular planes).

Image selection

The US images used in the study were collected by three sonographers highly experienced in gout (TC, VM, MG) using Esaote My Lab 70 and Esaote Class C machines with high frequency probes (6–18 MHz). Static images and videos were obtained from 13 patients with gout fulfilling the 2015 ACR/EULAR Criteria [8]. All patients had diagnostic confirmation by a positive polarized microscopy. We included joint, tendon, and cartilage images from hands (wrist and metacarpophalangeal joints), knees (joint and patellar tendon), ankles (tibiotalar and subtalar joint, achilles and tibialis posterior tendons), and feet (first metatarsophalangeal joint). In addition, a group of images was obtained from healthy subjects and patients with other rheumatic conditions (rheumatoid arthritis and osteoarthritis), from similar anatomic sites. The study was carried out according to regulations of the local ethics committee. All patients gave their informed consent.

First step: PANLAR US Study Group

During the review course of PANLAR in 2015, an image reading exercise was carried out with the participation of PANLAR US Study Group members. After an introductory

Table 1 Reliability results in PANLAR Study Group exercise

Reliability assessment	Tophus	Aggregates	DC	Erosions
Inter-reader				
Light's kappa	0.56	0.44	0.87	0.61
PABAK[a]	0.57	0.45	0.90	0.69
Intra-reader				
Light's kappa	0.76	0.86	0.90	0.80

[a]Average prevalence-adjusted and bias-adjusted kappa

session to review the definitions, participants were asked to read 60 images (50 static images and 10 videos), evaluating the presence/absence of any of the four elementary lesions: DC, tophus, aggregates, and erosions. In addition, a group of images was displayed twice to analyze the intra-reader reliability.

Second step: web-based exercise

After the first exercise, we decided to test the definitions in a larger group of sonographers, with more varied levels of experience, to further investigate our results. For this, we designed a specific website to display and rate videos. Rheumatologist specialized in US from Latin America and other regions were invited to participate by e-mail contact. After accessing the website, participants were asked to read an instructive manual describing the OMERACT definitions and provide personal data. It was remarked to stick to apply only the OMERACT definitions in each reading. The reading exercise consisted in the assessment of 50 videos (15 s of duration each), considering the presence/absence of any US gout lesion. Intra-reader reliability was evaluated in 15 videos, 2 weeks after the initial assessment.

Statistical analysis

Intra- and inter-reader reliabilities were calculated by the Cohen's kappa coefficient and classified according to Landis and Koch criteria. Kappa values of 0–0.20 were considered poor, 0.20–0.40 fair, 0.40–0.60 moderate, 0.60–0.80 good, and 0.80–1 excellent [13]. Inter-reader reliability was studied by calculating the mean kappa on all pairs (i.e., Light's kappa) [14]. Bias-adjusted and prevalence-adjusted kappa (PABAK) was calculated to overcome prevalence bias in kappa estimates [15]. Sonographers were stratified according to their US experience (defining high experience as at least ≥ 5 years of experience, ≥ 100 US assessments/month, and ≥ 10 US in gout patients/month), evaluating differences in intra-, inter-observer reliability and overall agreement.

Results

PANLAR Ultrasound Study Group reliability exercise

Sixteen members of the PANLAR US Study Group completed the exercise. All participants met the high US experience criteria [9.5 ± 2.2 (mean ± SD) years]. During the session, a total of 980 readings were performed. The mean Kappa inter-reader coefficients were moderate for aggregates and tophus, good for erosions, and excellent for DC (Table 1). All inter-reader Kappa values improved after adjusting for low prevalence (PABAK adjusted Kappa). The mean intra-reader kappa values ranged from good to excellent.

Reliability web-based multicentric exercise

Sixty-three sonographers from 12 countries (Argentina, Brazil, Bolivia, Colombia, Costa Rica, El Salvador, Mexico, Peru, Spain, United States, Uruguay and Venezuela) completed the web-based exercise. The group had a substantial US experience [median: 8 (p25–75 = 4–10) years]. A total of 3100 readings were performed. The prevalence of US lesions was: tophus (34%), aggregates (29%), erosions (22%), and DC (20%). Kappa coefficients and level of agreement are shown in Table 2. The mean Kappa inter-reader values were fair for aggregates, moderate for tophus and erosions, and good for DC. After adjusting for low prevalence using PABAK estimates, the inter-reader reliability

Table 2 Reliability results in web-based multicenter exercise

Reliability assessment	Aggregates	DC	Tophus	Erosions
Inter-reader				
Kappa	0.31	0.67	0.43	0.56
PABAK[a]	0.42	0.79	0.49	0.69
Agreement (%)	71	89	74	84
Intra-reader				
Kappa	0.62	0.85	0.69	0.77
Agreement (%)	83%	95%	85%	93%

k = Light's kappa, % = proportion of observed agreement

[a]Average prevalence-adjusted and bias-adjusted kappa

Table 3 Reliability according to sonographers' experience

Group	US experience (years)[a]	US assessments/month[a]	Gout US assessments/ month[a]	Reliability assessment	Aggregates		DC		Tophus		Erosions	
					%	*k*	%	*k*	%	*k*	%	*k*
High experience ($n=9$)	10 (8–12)	130 (130–174)	15 (10–20)	Inter-reader	68	0.27	93	0.73	74	0.44	88	0.62
				Intra-reader	83	0.64	95	0.84	84	0.61	99	0.94
Low experience ($n=53$)	8 (3–10)	52 (43–130)	4 (1–5)	Inter-reader	71	0.31	89	0.67	74	0.43	84	0.56
				Intra-reader	83	0.62	95	0.85	86	0.70	92	0.74

p25–75 percentile 25 and 75, *k* Light's kappa, % = proportion of observed agreement

[a]Expressed as median and IQR

coefficient increased. The mean intra-observer kappa values ranged from good to excellent in all lesions.

Interestingly, kappa values were similar for experienced and non-experienced sonographers, with the exception that experienced sonographers showed better intra-rater reliability when detecting erosions (Table 3).

Discussion

The relevance of US in the evaluation of gout was recognized in the new set of criteria of the American College of Rheumatology and the European League Against Rheumatism [8]. According to this publication, the presence of a DC in a symptomatic joint confirms MSU crystal deposition, avoiding the need of invasive procedures.

Although these recommendations meant an important step supporting US as a tool for gout evaluation, they only refer to the DC sign, and literature offers scarce data about US elementary lesions in gout. Besides, available studies of US in gout have used different definitions [16]. Considering the potential use of US findings as an outcome measure in future studies, the need for standardized definitions becomes an important aspect for research. In two recent publications, the OMERACT US Group developed the definitions of four US elementary lesions, including the DC, tophus, aggregates, and erosions. In the first study by Gutierrez et al., consensus-based definitions were obtained by the Delphi method, and their reliability was tested by the assessment of static images in a web-based exercise [11]. The reported inter-reader reliability was moderate to excellent for all the lesions, while DC showed the highest agreement and aggregates the lowest.

In the subsequent study, reliability was tested in a scanning exercise of patients with gout, reporting fair-to-good inter-observer agreement, depending on the type of lesion [12]. In regard to intra-observer reliability, both OMERACT studies reported moderate-to-excellent agreement for all lesions.

In our study, we were able to evaluate the reliability of this new core set of US definitions in a large group of sonographers through an image reading exercise. The results of our first exercise within PANLAR US Group were in line with the original OMERACT study, showing moderate-to-excellent kappa values in both inter- and intra-reader analyses. In our web exercise, the inter-reader reliability was good for DC ($k=0.79$) and erosions ($k=0.69$) and moderate for aggregates ($k=0.42$) and tophus ($k=0.49$). The intra-reader reliability was excellent for DC and good for the rest of the definitions.

The highest level of agreement was observed for the DC definition. This finding supports the key role of this definition, as it is probably the most specific US lesion for the diagnosis of gout [17, 18]. On the other hand, aggregates and tophus showed a moderate inter-reader agreement. As described by Terslev in the original article, this may be explained by a low specificity of these two definitions, which may have caused an overlap when the images were scored [12]. The definition of aggregates considers soft-tissue hyperechogenicity (as heterogeneous foci) that is usually present in gout, while the definition of tophus considers the presence of a circumscribed aggregation of crystals. We realize that both definitions are describing similar variants of MSU crystal deposition that may not only generate confusion, but also coexist in many of the cases. Finally, the definition of erosions showed good intra- and inter-reader reliabilities. This definition describes the interruption of the bone surface, a common finding in many inflammatory arthropathies. Because of its low specificity compared to the other lesions, erosions may provide a minor contribution for gout diagnosis. On the other hand, sonographers are used to evaluate this lesion, a fact that may have contributed to the good agreement we found.

To our knowledge, this is the study with the largest number of international participants evaluating the reliability of the new OMERACT US gout elementary lesions. Our main objective was to test the performance of the definitions in a large number of sonographers from different countries to estimate possible variations in their US training and experience.

A limitation of our study could be the reading of preselected images, a design that does not assess the sonographer's ability to obtain the image. In US exercises performed with patients, image acquisition and scanning technique often implicate lower reliability results. This was observed in the OMERACT reports, where the level of agreement for the DC definition differed on web-based compared to patient-based exercises [12]. In our study, we decided to use videos intending to overcome this limitation, as they may provide a more real-practice approach. In fact, the movement of the probe displayed in videos may help to distinguish the presence of MSU crystal deposition.

When we analyzed the levels of expertise, we did not found significant differences in the level of agreement, but this finding must be considered taking into account that the overall experience of our group was fairly good. In addition, there is a risk of bias that participants may use their own experience rather than following the OMERACT definitions. To overcome this, participants were asked to strictly apply the proposed definitions on each reading. In addition, we must mention that reading exercises may not be the best way to evaluate expertise levels, as experience may have strong impact on the acquisition of images and the scanning technique.

In conclusion, the reliability of the new OMERACT US definitions for elementary lesions in gout varied depending on the type of lesion. Our overall results are in line with the original OMERACT report, demonstrating acceptable levels of agreement among a large group of sonographers. The potential use of these definitions in clinical trials and daily practice may need further investigation in other important aspects, such as responsiveness and diagnostic accuracy.

Funding This study received no funding.

Compliance with ethical standards

Conflict of interest Tomas Cazenave declares that he has no conflict of interest. Victoria Martire declares that she has no conflict of interest. Anthony M. Reginato declares that he has no conflict of interest. Marwin Gutierrez declares that he has no conflict of interest. Christian Alfredo Waimann declares that he has no conflict of interest. Carlos Pineda declares that he has no conflict of interest. Javier Eduardo Rosa declares that he has no conflict of interest. Santiago Ruta declares that he has no conflict of interest. Oscar Sedano-Santiago declares that he has no conflict of interest. Ana Maria Bertoli declares that she has no conflict of interest. Marcelo Audisio declares that he has no conflict of interest. Cristina Hernandez-Diaz declares that she has no conflict of interest. Lucio Ventura-Rios declares that he has no conflict of interest. Maritza Quintero declares that she has no conflict of interest. Eugenio De Miguel declares that he has no conflict of interest. Ana Laura Alvarez-del-Castillo-Araujo declares that she has no conflict of interest. Andy Abril declares that she has no conflict of interest. Eliana Natalí Ayala-Ledesma declares that she has no conflict of interest. Edith Alarcon-Isidro declares that she has no conflict of interest. Maria Lida Santiago declares that she has no conflict of interest. Mariana Alejandra Pera declares that she has no conflict of interest. Cecilia Urquiola declares that she has no conflict of interest. Gustavo Rodriguez Gil declares that he has no conflict of interest. Lina Maria Saldarriaga Rivera declares that she has no conflict of interest. Cesar Cefferino declares that he has no conflict of interest. Mariana Benegas declares that she has no conflict of interest. Mario Enrique Diaz Cortes declares that he has no conflict of interest. Maximiliano Bravo declares that he has no conflict of interest. Diana Peiteado declares that she has no conflict of interest. Natalia Anahi Estrella declares that she has no conflict of interest. Roser Areny Micas declares that she has no conflict of interest. Jorge Saavedra Muñoz declares that he has no conflict of interest. Rodolfo del Carmen Arape Toyo declares that he has no conflict of interest. Maria Soledad Gálvez Elkin declares that she has no conflict of interest. Walter Javier Spindler declares that he has no conflict of interest. Clarisa Sandobal declares that she has no conflict of interest. Josefina Marin declares that she has no conflict of interest. Manuella Lima Gomes Ochtrop declares that she has no conflict of interest. Ricardo Pavao Ayala declares that he has no conflict of interest. Erika Roxana Catay declares that she has no conflict of interest. Guillermo Enrique Py declares that he has no conflict of interest. Gabriel Hector Aguilar declares that he has no conflict of interest. Yvonne Yona Rengel Colina declares that she has no conflict of interest. Carla Antonela Airoldi declares that she has no conflict of interest. Claudia Selene Mora-Trujillo declares that she has no conflict of interest. Maria Paula Kohan declares that she has no conflict of interest. Lorena Evelin Urioste Eguez declares that she has no conflict of interest. Concepción Castillo-Gallego declares that she has no conflict of interest. Jose Francisco Diaz-Coto declares that he has no conflict of interest. Patricio Tate declares that he has no conflict of interest. Carla Magali Saucedo declares that she has no conflict of interest. Oscar Vega-Hinojosa declares that he has no conflict of interest. Cristian Jonatan Troitiño declares that he has no conflict of interest. Maria Florencia Marengo declares that she has no conflict of interest. Priscila Maria Marcaida declares that she has no conflict of interest. Irene Monjo Henry declares that she has no conflict of interest. Roberto Muñoz-Louis declares that he has no conflict of interest. Carla Solano declares that she has no conflict of interest. Felix Reinaldo Fernandez Castillo declares that he has no conflict of interest. Cesar Enrique Graf declares that he has no conflict of interest. Mara Guinsburg declares that she has no conflict of interest. Maria Julia Santa Cruz declares that she has no conflict of interest. David Alejandro Navarta Ortiz declares that he has no conflict of interest. Magaly Alva Linares declares that she has no conflict of interest. Marcos Gabriel Rosemffet declares that he has no conflict of interest.

Research involving human and/or animal participants All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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