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OMERACT definition and reliability assessment of chronic ultrasound lesions of the axillary artery in giant cell arteritis

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ABSTRACT

Objectives: To define chronic ultrasound lesions of the axillary artery (AA) in long-standing giant cell arteritis (GCA) and to evaluate the reliability of the new ultrasound definition in a web-based exercise.
Methods: A structured Delphi, involving an expert panel of the Large Vessel Vasculitis subgroup of the Outcome Measures in Rheumatology (OMERACT) Ultrasound Working Group was carried out. The reliability of the new definition was tested in a 2-round web-based exercise involving 23 experts and using 50 still images each from AA of long-standing and acute GCA patients, as well as 50 images from healthy individuals.
Results: The final OMERACT ultrasound definition of chronic changes was based on measurement and appearance of the intima-media complex. The overall reliability of the new definition for chronic ultrasound changes in longstanding GCA of the AA was good to excellent with Light's kappa values of 0.79-0.80 for inter-reader reliability and mean Light's-kappa of 0.88 for intra-reader reliability. The mean inter-rater and intra-rater agreements were 86-87% and 92%, respectively. Good reliabilities were observed comparing the vessels with longstanding versus acute GCA with a mean agreement and kappa values of 81% and 0.63, respectively.
Conclusion: The new OMERACT ultrasound definition for chronic vasculitis of the AA in GCA revealed a good to excellent inter- and intra-reader reliability in a web-based exercise of experts.

1. Introduction

Giant cell arteritis (GCA) is the most common primary systemic vasculitis, which occurs predominantly in Caucasian populations [1]. Extracranial involvement such as vasculitis of the axillary artery (AA) occurs in up to 80% of patients with GCA [2], and may be particularly detected by ultrasound. Patients with predominantly large-vessel GCA often present clinically with polymyalgia rheumatica (PMR) and constitutional symptoms, and are affected by a diagnostic delay as compared to patients with predominantly cranial GCA [2–4]. Furthermore, patients with PMR are often managed in primary care; and only refractory cases are referred to rheumatologists for further diagnostic work-up [5]. These patients have already been treated for many weeks with glucocorticoids when they are first seen by a rheumatologist, which is known to affect the results of all imaging modalities of joints and vessels [6,7]. Evaluating the presence of vasculitis with ultrasound in extracranial arteries, like the AA, is of clinical importance not only for diagnostic purposes as suggested by European League Against Rheumatism (EULAR) and British Society for Rheumatology (BSR) recommendations but also for prognostic stratification [8,9]. Patients with extracranial GCA have higher relapse rates and higher cumulative glucocorticoid doses compared to patients with cranial manifestations only [10]. The application of ultrasound for the assessment of AA involvement in the diagnosis of acute GCA is well established [11–13], whereas the value of ultrasound of AA in patients with chronic long-standing or treated GCA still needs to be investigated. Previous studies investigating the follow-up of GCA showed that the IMT of the AA does not return to normal in all patients, while the IMT of the temporal arteries commonly does [14].

In order to test the diagnostic value of ultrasound of the AA in patients with long-standing GCA, as well as to use this technique as a possible outcome measure in treatment studies, a definition for ultrasound lesions suggestive of chronic GCA at AA had to be developed. This was carried out in the present project by the Large Vessel Vasculitis (LVV)-subgroup of the Outcome Measures in Rheumatology (OMERACT) Ultrasound Working Group. Subsequently, the definition was tested in a web-based reliability exercise.

2. Methods

2.1. Study Design

This study was conducted in accordance with the OMERACT Filter 2.1 Instrument Selection Algorithm (OFISA) [15] and the OMERACT methodology developed for selecting imaging instruments [16–20]. and was supervised by the two OMERACT ultrasound mentors of the subgroup (AI, GB)

Our study complies with the Declaration of Helsinki. Use of images from patients for the reliability exercise was approved by the local ethics committee of the Berlin Board of Physicians (Eth-52/16).

Twenty-three physicians of the OMERACT Ultrasound LVV-subgroup were invited by email to participate. They were from 15 countries (Austria, Czech Republic, Denmark, France, Germany, Italy, Norway, Poland, Portugal, Slovenia, Spain, Switzerland, The United States of America, The Netherlands and UK). All of them were board certified rheumatologists with long-standing experience in LVV ultrasound.

2.2. Delphi exercise

A systematic literature review [21] had already been conducted as part of the project for developing definitions of elementary ultrasound lesions in acute GCA [22]. However, no definition was found on ultrasound lesions in long-standing GCA. We therefore invited the 23 experts of this project to propose a new definition for chronic ultrasound lesions of long-standing vasculitis of AA in GCA in an open Delphi round. Experts could supply their ideas on suitable elements for this definition incorporating B-mode imaging, Power Doppler and IMT measurement.

Based on the feedback from the open round, a WORD™-based questionnaire was developed including all proposals for a definition of elementary ultrasound lesions in long-standing vasculitis of AA in GCA. In order to evaluate and modify these proposals, we invited the same 23 experts to all subsequent Delphi rounds. The questionnaire for the second Delphi round included 20 statements (**supplementary data S1**) which were subdivided in four sections: B-mode image, Doppler-mode image, IMT measurement protocol, as well as a dichotomous question if measuring the resistance index might be of help, which was included due to one member by request.

Experts were asked to rate each definition on a 1–5 Likert scale, with 1=strongly disagree and 5=strongly agree, as well as to comment, modify or propose new definitions. A consensus was defined as a score of 4 or 5 provided by ≥75% of experts. Further, we questioned the participants to provide an overall ranking of the definition ranging from 1 to 5, 1 being the best definition, 5 the worst.

Statements achieving a ≥75% agreement in the second round, and where suggestions for an improvement of wording were provided, were rephrased and re-sent to the experts in the subsequent Delphi round. Statements with <75% agreement in the first round were excluded from subsequent rounds. Up to two reminders were sent out to the experts if they had not responded within the given time limit of 30 days. The answers of the first Delphi round were

summarised with the percentage of agreement to each statement. For the second Delphi round, all comments of the panellists were anonymised and re-sent together with a revised questionnaire to those experts who had responded in the first round.

2.3. Inter-rater and intra-rater web-based reliability exercise

Three members (WAS, SC and VSS) of the OMERACT Ultrasound LVV- subgroup provided a total of 150 ultrasound images of AA: 50 from patients with acute GCA (disease duration < 7 days, high acute phase reactants, and/or GCA-related symptoms), 50 from long-standing GCA (disease duration > 6 months, all in clinical remission) and 50 from healthy individuals (Fig. 2).

Each image was derived from a single patient. Images were obtained from three different ultrasound machine brands (Esaote, GE and Hitachi) using linear transducers with maximum grey scale frequencies of 8-18 MHz.

Image acquisition was performed in each centre according to a previously published scanning protocol [23]. Fifteen images from each of the above-mentioned groups displayed also IMT measurements. All GCA patients met the expanded ACR classification criteria for GCA [3], and the diagnosis was confirmed either by temporal artery biopsy or on a clinical basis, including ultrasound and clinical follow-up [3]. The images and videos were collected by a facilitator of the group (SC) who constructed an electronic database. A link with the web-based exercise using Research Electronic Data Capture (REDCap) [24] was sent to the same 23 rheumatologists who participated in the Delphi exercise asking them to apply the new definition as well as the previously published definitions for acute GCA and normal AA [22] in order to decide whether each image was suggestive of long-standing or acute GCA, or normal. All definitions were displayed above each ultrasound image (Fig. 1). Two weeks after the first evaluation, the participants received the same images in a different order for evaluating the intra-rater agreement. All images were anonymised for patient's data, the centre where the image was obtained as well as ultrasound machine settings and manufacturer.

2.4. Statistical analysis

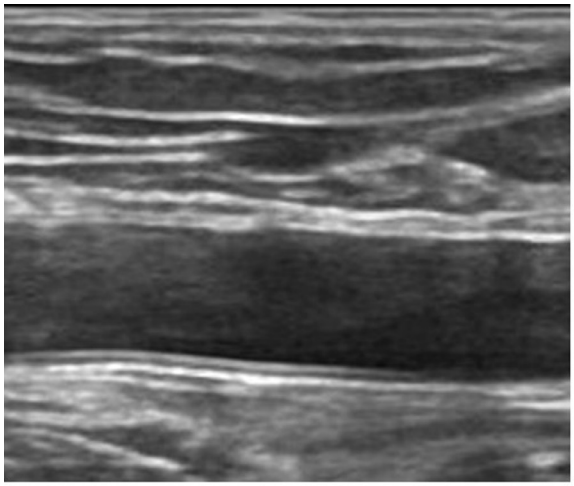
For the Delphi, only descriptive statistics were applied. Intra-rater and inter-rater reliabilities were calculated using the kappa coefficient (κ). Intra-rater reliability was assessed by Cohen's κ, and inter-rater reliability was studied by calculating the mean κ on all pairs (ie, Light's κ) [25]. Kappa coefficients were interpreted according to Landis and Koch with κ values of 0–0.2 considered poor, 0.2–0.4 fair, 0.4–0.6 moderate, 0.6–0.8 good and 0.8–1 excellent [26]. The percentage of observed agreement (i.e., the percentage of observations that obtained the same score) and prevalence of the observed lesions were also calculated. Analyses were performed using R Statistical Software (Foundation for Statistical Computing, Vienna, Austria).

3. Results

3.1. Delphi exercise

There was a total of six Delphi rounds. Of the 23 experts invited to the first, open Delphi round, 11 (47.8%) sent a proposal for defining ultrasound elementary lesions in chronic vasculitis of the AA in GCA. Response rate for Delphi rounds 2 to 6 was 100% for each round, except for round 3, where 21 out of 23 participants replied (91% response rate).

In the 3rd Delphi round only five definitions were left, which had been also adjusted on the basis of the comments of the participants. In Delphi round 4 two definitions were left, which due



	Definition of US appearance of normal Axilary artery	Definition of US appearance of vasculitis- "Halo Sign"	Definition of US appearance of Chronic Vasculitis changes
Axillary artery	Pulsating, hardly compressible artery with anechoic lumen; the intima-media complex presents as a homogenous, hypoechoic or anechoic echostructure delineated by two parallel hyperechoic margins ('double line pattern'), which is surrounded by mid-echoic to hyperechoic tissue.	Homogenous, hypoechoic wall thickening, well delineated towards the luminal side, visible both in longitudinal and transverse planes, most commonly concentric in transverse scans.	Mostly homogenous, mid- to hyperechoic long-segmental thickening of the intima-media complex (IMC) > 0.9 mm, displaying several visible lines with loss of the typical double line pattern, well delineated towards the luminal side, visible both in longitudinal and transverse planes, most commonly concentric in transverse scans. Doppler sonography can be of help depicting stenosis, collaterals and occlusion. Atherosclerotic changes may coexist.

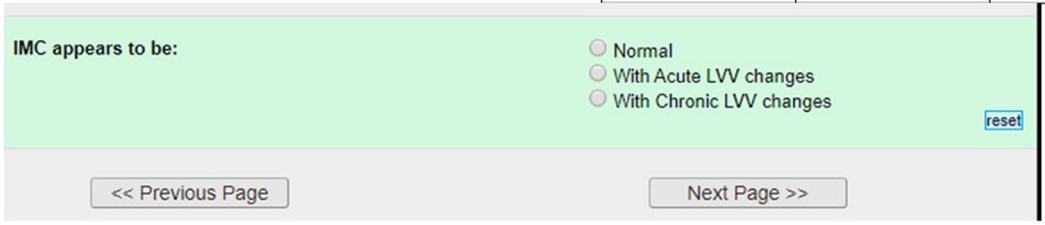


Fig. 1. Example of the web-based exercise image rating
The ultrasound image was shown, including the new definitions for chronic GCA as well as previously published definitions of acute GCA and normal axillary artery.

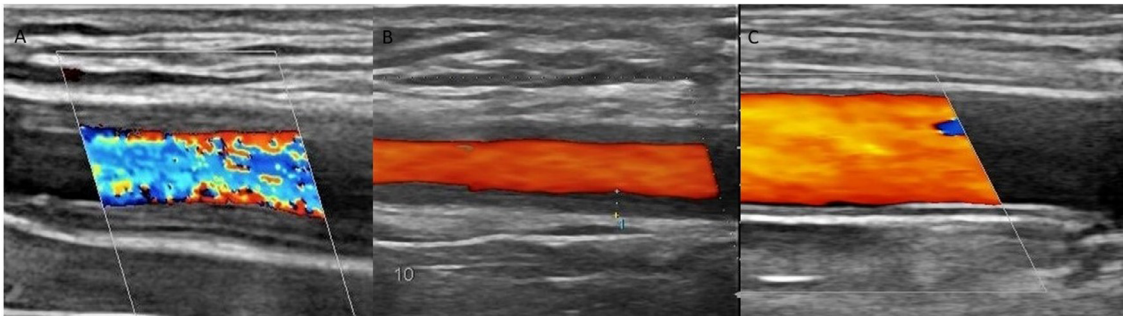


Fig. 2. Ultrasound images of the axillary artery from the web-based exercise
Three longitudinal ultrasound images of the axillary artery from each group: A: chronic changes of the intima-media complex (IMC) in long-standing giant cell arteritis displaying several visible lines within the IMC, B: acute vasculitis in new-onset giant cell arteritis with hypoechogenic IMC, C: normal axillary artery.

to their similarity were fused to one definition in Delphi round 5. The definition reached an agreement of 85% with a mean Likert Scale of 4.13.

In Delphi round 5, 16 participants (70%) commented, that they would prefer to have an IMT cut-off value for long-standing GCA incorporated into the final definition. After Delphi round 5, the results of a study became available reporting that an IMT cut-off value of 0.87mm best discriminated between patients with and without chronic vasculitis at the AA [27].

After the IMT cut-off has been presented, we set up a 6th Delphi round in order to vote for the inclusion of the IMT value into the definition. The final agreement to the new definition was 91.3% with a median Likert scale of 5 (range 3-5). See Table 1 for the new OMERACT ultrasound definition of vasculitis at the AA in patients with long-standing GCA along with the already published definitions for acute GCA and the normal appearance of AA [22].

3.2. Web-based exercise on ultrasound images

All 23 group members participated in the web-based exercise in round 1 and round 2 (100%). The overall reliability of the new OMERACT definition for the ultrasound appearance of long-standing GCA of the AA was good to excellent with Light's kappa values of 0.79-0.80 for inter-reader reliability and excellent for the intra-reader reliability with mean Light's-kappa values of 0.88 (Table 2). Sub-analyses were done on long-standing and acute vasculitis as well as considering long-standing vasculitis and healthy individuals only. In addition, we tested the reliability in patients with and without measurements of the IMT thickness separately (see Table 2). Similar to the overall results, excellent inter- and intra-reader agreements were observed comparing normal arteries with either acute or chronic GCA and arteries without measurements provided (Table 2 and 3). The inter-rater agreement was good comparing images of acute and long-standing GCA with and without measurements, while the intra-rater agreement was found to be excellent (Table 2 and 3).

4. Discussion

The group has previously shown, that ultrasound of the AA and temporal arteries is an important and reliable imaging modality in the diagnosis of GCA [22,23]. In the present paper we propose a consensus-based definition for ultrasound appearance of chronic vasculitis of the AA in long-standing GCA, and assessed the reliability of this new definition in a Web-based exercise. The overall inter- and intra-observer agreement of ultrasound images from acute and chronic GCA, as well as normal AA was good to excellent when applying the new OMERACT definition and the previously published ultrasound definitions for acute GCA [22]. This new definition will facilitate studies on the diagnostic value of ultrasound to detect chronic ultrasound lesions in GCA and will form the basis for an outcome measurement instrument for clinical trials in GCA.

The reliability for chronic ultrasound changes is similar to the results for differentiating acute lesions from normal arteries (13). Furthermore, in the present study chronic GCA changes of the AA compared to normal AA showed excellent inter and intra-observer reliabilities, as well (Table 2 and 3). When conducting subgroup analysis on ultrasound images of acute and chronic ultrasound vasculitis the reliability was found to be moderate and lower than in other analyses (Table 2). The difference is that echogenicity on ultrasound is increased and that we see the multilinear pattern on IMT in chronic changes, in comparison to ultrasound findings in acute GCA. One possible explanation is that more edema and lymphocytic infiltrates are present in the acute phase of the vessel wall, while remodeling may occur in the chronic phase. It is well known that the echogenicity and morphology of the IMT can be influenced by the ultrasound equipment (machine and/or probe), settings and scanning technique. As the collected images originated from three different centers, using three different ultrasound machines and anonymized images, our results are even more robust, somehow it may explain the lower agreement between chronic and acute ultrasound vasculitis changes, as echogenicity can be substantially dependent of equipment and settings (29).

Table 1
Ultrasound definitions of normal, acute and chronic GCA of the axillary artery.

Definitions	Definition of US key lesions of normal axillary artery [22]	Definition of US key lesions of acute GCA- "Halo Sign" [22]	Final definition of US key lesions in chronic GCA of the axillary artery
	Pulsating, hardly compressible artery with anechoic lumen; the intima-media complex presents as a homogenous, hypoechoic or anechoic echostructure delineated by two parallel hyperechoic margins ('double line pattern'), which is surrounded by mid-echoic to hyperechoic tissue.	Homogenous, hypoechoic wall thickening, well delineated towards the luminal side, visible both in longitudinal and transverse planes, most commonly concentric in transverse scans.	Mostly homogenous, mid- to hyperechoic long-segmental thickening of the intima-media complex (IMC) > 0.9 mm, displaying several visible lines with loss of the typical double line pattern, well delineated towards the luminal side, visible both in longitudinal and transverse planes, most commonly concentric in transverse scans. Doppler sonography can be of help depicting stenosis, collaterals and occlusion. Atherosclerotic changes may coexist.

Table 2
Inter-rater agreement and reliability for the chronic and new onset ultrasound vasculitis lesions in axillary arteries.

Section	Number of evaluated images	Agreement mean in %, (range)	Light's κ mean (range)
Overall agreement	150	87% (66–99)	0.8 (0.50–0.99)
Normal vs Acute	100	91% (74–100)	0.84 (0.58–1.00)
Normal vs Chronic	100	88% (67–100)	0.79 (0.46–1.00)
Acute vs Chronic	100	81% (49–99)	0.63 (0.13–0.98)
Images without measurements	105	87% (67–100)	0.81 (0.52–1.00)
I Images with measurements	45	85% (58–100)	0.78 (0.38–1.00)

*Calculated as pathological lesions out of 100 presented images and/or videos.

Table 3
–Intra–rater agreements and reliability for the chronic and new onset ultrasound vasculitis lesions in axillary arteries.

Section	Number of evaluated images	Intra–rater agreement *mean in % (range)*	Intra–rater reliability Light's κ, *mean* (range)
Overall agreement	150	92% (84–100)	0.88 (0.75–0.99)
Normal vs Acute	100	94% (81–100)	0.9 (0.70–1.00)
Normal vs Chronic	100	93% (67–100)	0.87 (0.65–1.00)
Acute vs Chronic	100	90% (80–100)	0.79 (0.55–0.98)
Images without measurements	105	92% (82–100)	0.88 (0.72–1.00)
I Images with measurements	45	92% (81–100)	0.88 (0.72–1.00)

It is reported that the ultrasound 'halo' sign of temporal arteries disappears in the majority of patients after 2–4 weeks of glucocorticoid therapy (8), while studies of the AA indicate, that in two thirds of GCA patients an increased IMT persists, despite glucocorticoid treatment [28]. An increasing number of centers is offering fast-track clinics, where ultrasound assessment of the temporal and axillary arteries is performed within a few days after referral [29]. Although the number of fast-track clinics is increasing, still, several patients are referred to rheumatology assessment only when they have been on glucocorticoids for several days or weeks. Our definition thus has immediate practical relevance and may lead to a more consistent detection of GCA of the AA in these patients.

We incorporated a IMT cut-off of 0.9mm in our definition, given that such a value was specifically requested by the experts. During the Delphi exercise, the results of a study became available who demonstrated a sensitivity of 61% and a specificity of 96% for the above-mentioned cut-off to separate GCA patients with chronic vasculitis of the AA from those without AA involvement and healthy controls. While that study was conducted by some of the group members (CD, WS and VSS), it was not part of the current project and is therefore published elsewhere [30].

Vasculitic changes of the AA can also be observed in patients with relapsing PMR [31], who are then often re-classified as GCA. The AA is the most commonly affected artery in patients with LV-GCA according to ultrasound studies (6,19), it is easy accessible for ultrasound evaluation [29] and only requires 7,5-15 MHz probes [9] that are available in the majority of rheumatology departments. All of the above emphasize the importance of our findings.

Our study has limitations. First, we had no data from literature and needed to start with an open Delphi round to collect expert opinions on the appearance of chronic ultrasound changes in GCA. Second, for the group with long-standing GCA, we only had images from patients with disease duration > 6 months and do therefore not know whether our definition performed equally well in groups with disease duration 1-6 months. Up to now, we do not know when ultrasound signs of acute GCA "transform" into the chronic pattern. A study of one of the authors to address this issue is currently underway (VSS). We did not retrieve any data on demographics, clinical manifestations, comorbidities or treatment from patients whose images were used for reliability assessment given that the purpose of this exercise was to test the reproducibility of the new OMERACT definition(s) rather than examining the possible influence of clinical data on IMT thickness. Lastly, we only tested stored ultrasound images, precluding assessment of acquisition reliability. We can therefore not exclude that the reliability of the new definition is lower when patients with chronic GCA are evaluated in routine clinical practice. The next step is to assess the reliability of the definition for chronic AA in GCA in a patient-based exercise including the impact of image acquisition.

5. Conclusion

In conclusion, an international expert consensus was reached using the OMERACT imaging methodology for the definition of ultrasound appearance of chronic vasculitis of the AA in GCA. While this definition can be used immediately in practice for assessing and reporting chronic vasculitis at AA, next steps are to investigate the performance of this definition in follow-up studies and to develop a score in order to use ultrasound as an outcome measure in future trials of GCA.

Declaration of Competing Interest

None of the authors declare any competing interest with the present study.

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Supplementary materials

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