Development of a Core Set of Outcome Measures for Large-vessel Vasculitis: Report from OMERACT 2016

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ABSTRACT. ***Objective.*** Among the challenges in conducting clinical trials in large-vessel vasculitis (LVV), including both giant cell arteritis (GCA) and Takayasu arteritis (TA), is the lack of standardized and meaningful outcome measures. The Outcome Measures in Rheumatology (OMERACT) Vasculitis Working Group initiated an international effort to develop and validate data-driven outcome tools for clinical investigation in LVV.

Methods. An international Delphi exercise was completed to gather opinions from clinical experts on LVV-related domains considered important to measure in trials. Patient interviews and focus groups were completed to identify outcomes of importance to patients. The results of these activities were presented and discussed in a "Virtual Special Interest Group" using telephone- and Internet-based conferences, discussions through electronic mail, and an in-person session at the 2016 OMERACT meeting. A preliminary core set of domains common for all forms of LVV with disease-specific elements was proposed.

Results. The majority of experts agree with using common outcome measures for GCA and TA, with the option of supplementation with disease-specific items. Following interviews and focus groups, pain, fatigue, and emotional effect emerged as health-related quality of life domains important to patients. Current disease assessment tools, including the Birmingham Vasculitis Activity Score, were found to be inadequate to assess disease activity in GCA and standardized assessment of imaging tests were felt crucial to study LVV, especially TA.

Conclusion. Initial data from a clinician Delphi exercise and structured patient interviews have provided themes toward an OMERACT-endorsed core set of domains and outcome measures. (First Release September 1 2017; J Rheumatol 2017;44:1933–7; doi:10.3899/jrheum.161467)

Key Indexing Terms:
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Giant cell arteritis (GCA) and Takayasu arteritis (TA) are large-vessel vasculitides (LVV) that share similar features[1]. Clinical research in LVV has been hindered by the lack of standardized outcome measures[2]. The Outcome Measures in Rheumatology (OMERACT) Vasculitis Working Group leads efforts to advance development of outcome measures in vasculitis, including LVV. During the 2016 OMERACT meeting, a virtual "Special Interest Group" was conducted to discuss the current research findings and propose a preliminary core set of domains. The main discussion points were (1) results of the international LVV Delphi exercise, (2) findings of the qualitative studies in TA, and (3) current work on LVV disease activity and damage measures. Following the discussion, a preliminary core set of domains common to LVV with disease-specific elements was proposed.

MATERIALS AND METHODS/RESULTS

Delphi exercise. Given the lack of international consensus on outcome measures to assess LVV, the LVV Task Force conducted an international Delphi exercise to obtain experts' opinions regarding important disease domains for the assessment of disease outcomes in LVV[2a]. Ninety-nine experts were involved. Key findings emerging from this exercise were that (1) many domains were common to TA and GCA, but some were distinctly identified with one or the other disease; (2) patient's global assessment (PtGA) was accepted as a tool to assess patient-reported outcomes (PRO) in LVV; and (3) the majority of experts (at least 70%) agreed to have a common outcome measure tool for both GCA and TA, but that such a measure can also be supplemented by disease-specific items for trials of GCA and TA.

Patient interviews/qualitative research. Generic PRO instruments such as the Medical Outcomes Study Short Form-36 and PtGA have been previously examined in patients with LVV[3,4,5,6]. However, these instruments often cannot identify essential disease-specific domains that are of high importance to patients with LVV. The LVV Task Force has completed individual interviews and focus groups with patients in the United States and Turkey to identify key health-related domains that patients consider important in TA[6a]. Thirty-one patients participated (12 patients from the United States and 19 patients from Turkey). Purposive sampling was used to include patients with various disease duration and severity. Free listing and pile sorting methods as well as extensive qualitative review of the transcripts were analyzed using Nvivo (Version 10, QSR International Pty, Ltd.). The most salient terms and common themes that emerged were pain and discomfort, fatigue and low energy levels, and emotional effect. Similar qualitative research is now being planned for patients with GCA to identify similarities and differences between the 2 diseases.

The OMERACT Special Interest Group (SIG) decided that these data about patient preferences should be combined with the results of the Delphi about physician opinions to form the basis of the draft core set of domains.

Assessment of disease activity. There currently exists no clear definition of disease activity in LVV. A systematic review of disease activity and outcome measures was previously published by the OMERACT LVV Task Force[7]. Several disease activity assessment tools have been used in clinical trials of LVV. These tools often use a combination of clinical symptoms, cumulative glucocorticoid dose/duration, and acute-phase reactants. Criteria used by a US National Institutes of Health group for active disease[8], the Birmingham Vasculitis Activity Score (BVAS)[9], the Disease Extent Index for TA[10], and the Indian TA Score 2010[11] have been used in clinical research for TA[12,13,14]. A similar disease-specific tool does not exist for GCA and a recent study led by investigators within the OMERACT Vasculitis Working Group found BVAS to have limited utility in GCA[15]. A combination of clinical symptoms, glucocorticoids dose or duration, and/or BVAS has been used in clinical trials of GCA[13,16,17,18].

Imaging has emerged as a promising diagnostic and critical tool to follow the disease course in LVV. Imaging modalities for LVV include color duplex ultrasonography[19,20,21], computed tomography (CT) angiography[22,23], magnetic resonance angiography[24,25,26], and 18F-fluorodeoxyglucose positron emission tomography either alone or with CT[27,28,29]. These modalities differ in terms of test characteristics, cost, exposure to radiation, and availability. There is a need for formal validation of imaging modalities for correlation with activity, damage, and outcome in LVV. There are also major uncertainties concerning the meaning of radiographic changes in arterial walls (thickening, enhancement, high signal) regarding disease activity and prognosis.

Although acute-phase reactants, including erythrocyte sedimentation rate and C-reactive protein, could be of use to assess disease activity[30,31] in GCA, and are of unclear utility in TA[32], the exact role of these biomarkers in disease assessment in LVV remains uncertain.

Assessment of disease damage. Besides the TA Damage Score, no other disease-specific damage indices have been validated for LVV[33]. While the Vasculitis Damage Index (VDI) has been used to assess damage in LVV[34,35], this tool is nonspecific (i.e., it does not identify specific sites of involvement or laterality), includes all-cause damage (such as damage unrelated to vasculitis or its treatment), and contains items that are irrelevant to LVV and are instead related to the ENT, pulmonary, and renal systems. The OMERACT LVV Task Force recently completed validation studies of VDI and a new LVV damage tool called the Large Vessel Vasculitis Index of Damage in GCA and TA. Preliminary results showed that the majority of patients with GCA and TA have a significant damage burden early in the disease course; however, unlike GCA, in which damage is predominantly due to treatment, damage in TA is primarily related to the disease.

DISCUSSION

Data and insights expected from trials conducted recently/ongoing. Despite the lack of standardized outcome measures, several randomized clinical trials of LVV have been conducted recently with varying success. In particular, 4 major clinical trials examining the role of various biologic medicines are of interest: (1) a randomized trial of abatacept for the treatment of LVV[36,37], (2) a phase II randomized trial of tocilizumab in GCA[18] and TA[38], (3) a phase III randomized trial of tocilizumab in GCA (GiACTA)[39], and (4) a phase III randomized trial of sirukumab in GCA (SIRRESTA; ClinicalTrials.gov identifier: NCT02531633). Other investigational drugs are being analyzed for the treatment of LVV such as ustekinumab (NCT02955147), baricitinib (NCT03026504), and anakinra (NCT02902731). Outcome definitions for these clinical trials are similar and use a combination of relapse-free survival, cumulative glucocorticoid dose/duration, physician's global assessment, acute-phase reactants, and PRO. Using patients' symptoms and acute-phase reactants as indicators of disease activity may prove suboptimal given the potential for ongoing inflammation in asymptomatic patients[8] and the lack of appropriate specificity and sensitivity of acute-phase reactants[30,40]. Additionally, using a dichotomous outcome measure such as active disease versus remission may miss a scale of response that is not necessarily identified in relapse-free survival assessment. Finally, if the recently studied biologic therapies prove to be highly effective as glucocorticoid-sparing agents in LVV, reassessment may be needed when

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using cumulative glucocorticoid dose/duration as an outcome measure.

The OMERACT SIG group recognizes that new measures of disease activity in LVV need to be developed that incorporate several approaches, especially including PRO and imaging. It is anticipated that analysis of data from recently completed and ongoing clinical trials in GCA and TA will help advance disease assessment in LVV.

Proposal of a preliminary core set of domains in LVV. As previously mentioned, the majority of experts in LVV voted through the Delphi exercise to have common outcome domains and measures for GCA and TA supplemented with disease-specific elements. The benefits to having common measures include ease of implementation, and potential applicability to other LVV such as idiopathic aortitis.

During the OMERACT LVV SIG, the group proposed a preliminary set of core domains for use in clinical trials of LVV (Figure 1) that includes a core set of domains with additional disease-specific elements. This approach to domain selection is congruent with the OMERACT Filter 2.0 methodology, including the 2 major concepts of effect of health conditions and pathophysiologic manifestations, and the 3 mandatory core areas of death, life effect, and pathophysiological manifestations.

Summary and future research agenda. Steady progress has been made to develop a set of outcome measures useful in clinical trials of LVV. The Delphi exercise identified domains of interest and outcome measures for the assessment of LVV and highlighted the importance of having a common set of domains and outcome measures for GCA and TA, supplemented with disease-specific elements. The qualitative research identified domains of importance to patients from their own perspectives. Validation studies of the current disease activity and damage tools including BVAS and VDI underlined the shortcomings of these assessment tools in LVV. Table 1 shows the OMERACT checklist items that have been completed so far to draft an initial core set of domains and the future steps that have been planned. It is the ultimate goal of the OMERACT Vasculitis Working Group LVV Task Force to develop an OMERACT-endorsed, internationally recognized core set of outcome measures for LVV for use in clinical trials.

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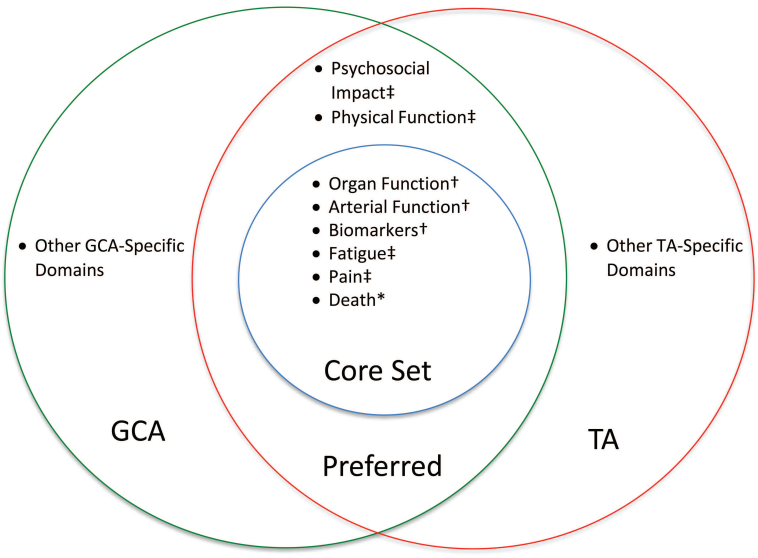

Figure 1. A draft core set (domains requiring some representation by an outcome measures in all trials) and additional preferred domains (1) common to both GCA and TA, and (2) separate disease-specific domains. The suggested core domains fall under the mandatory core areas of OMERACT filter 2.0: *Death. ‡Life impact. †Pathophysiologic manifestations. GCA: giant cell arteritis; TA: Takayasu arteritis.

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Table 1. OMERACT master checklist for developing a core outcome measurement set for large-vessel vasculitis (LVV), and steps planned by the OMERACT Vasculitis Working Group Large-vessel Vasculitis Task Force.

#	Item*	OMERACT Checklist Item	Completed
Assembly of working group and work plan			
1.	3.B.1	Forming an OMERACT Working Group	x
2.	3.B.2	Stakeholder groups and their contacts identified	x
3.	3.B.3	Thorough review of domain and instruments previously used	x
4.	3.B.4	Implementation of Delphi and/or focus groups	x
Core domain set selection			
5.	3.C.1.1	Definition of context: setting (scope)	x
6.	3.C.2.1	Deciding on the inclusion of resource use	x
7.	3.C.3.1	Literature review of domains (and instruments), part 1: what has been measured?	x
8.	3.C.4.1	Identification or definition of other domains of interest	x
9.	3.C.5.1	Formulation of draft core domains — at least 1 per core area	x
10.	3.C.6.1	Formulation of core contextual factors	Pending
11.	3.C.7.1	Formulation of core adverse events, if any	Pending
	Working group vote	Working group agrees they have draft core domain set prepared	Pending
12.	3.C.8.1	OMERACT consensus on core domain set and timeline for update cycle	Pending
Future steps for the OMERACT Vasculitis Working Group Large-vessel Vasculitis Task Force			
1. Report findings from a Delphi exercise, qualitative studies in TA, and analyses of damage assessment tools in LVV.			
2. Conduct qualitative interviews with patients with GCA to identify key themes and domains of high importance to patients with GCA.			
3. Further determine the differences and commonalities between GCA and TA regarding disease experience that can assist in identifying disease-specific domains of interest.			
4. Assess the need to develop a disease-specific PRO for GCA and/or TA.			
5. Incorporate data on the utility of imaging modalities in GCA and TA into the outcome development program for LVV.			
6. Finalize a draft core set of domains and identify the best candidate tools to measure these domains.			
7. Test the draft core set of outcomes in cohorts and trials.			

*Item number in the OMERACT 2.0 Handbook. OMERACT: Outcome Measures in Rheumatology; GCA: giant cell arteritis; LVV: large-vessel vasculitis; TA: Takayasu arteritis; PRO: patient-reported outcomes.

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