Current Status of Outcome Measures in Vasculitis: Focus on Wegener's Granulomatosis and Microscopic Polyangiitis. Report from OMERACT 7

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ABSTRACT. The complexity of assessing disease activity, disease status, and damage in the vasculitides reflects the multisystemic pathologic manifestations of these often chronic illnesses. Major progress has been made in the past decade in the development of validated and widely accepted outcome measures for use in clinical trials. Over time, these tools have been regularly revised, expanded, and supplemented with new measures of disease prognosis and damage. As a result clinical research in this area has become increasingly complex. This article critically reviews the current status of tools for assessing disease activity and damage in "ANCA-associated" vasculitides (Wegener's granulomatosis and microscopic polyangiitis), summarizes the current level of validation of each measure, addresses central problems and controversies to be considered during development of new vasculitis assessment tools, and proposes a series of research agendas for consideration by the vasculitis research community. (J Rheumatol 2005;32:2488–95)

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Major progress has been made in the past decade in the design and conduct of therapeutic clinical trials of vasculitis. Clinical research in vasculitis has evolved from single-center, open-label case series to larger, randomized, multicenter, controlled clinical trials. The formation of international collaborative research groups has been a major factor in the success of these trials. Validated outcome measures for use in clinical trials have developed in parallel to this initiative. The initial set of outcome tools for measuring vasculitis disease activity and damage were widely accepted and utilized in trials. They have also been regularly revised, expanded, and supplemented with new measures of disease prognosis. However, the introduction of these additional outcome measures for vasculitis has made clinical vasculitis research increasingly complex.

Multiple different outcome measures for vasculitis disease assessment are currently in use. While these measures share many similarities, they are sufficiently different as to make comparison among trials and sharing of data problematic. Problems include whether a single disease activity and outcomes tool can be utilized for illnesses that are clinically distinct; there is also controversy about how to measure disease activity and damage and define disease states and classes. Moreover, with the increased size and greater sophistica-

tion of treatment trials, the inherent deficiencies of each measure have become more apparent.

There is consensus in the vasculitis research community that uniform, improved, and universally accepted instruments for use in future primary systemic vasculitides trials would be highly desirable. Several members of the vasculitis research community with experience in the development and use of disease assessment tools formed a special interest group in anticipation of OMERACT 7, with the goal of reviewing assessment instruments for disease activity and damage in vasculitis and revising them, or developing new consensus tools as needed. This project is sponsored by the recently formed Vasculitis Clinical Research Consortium (VCRC).

A first step for the VCRC-OMERACT initiative was to revisit existing tools in order to identify advantages and weaknesses of the respective instruments. The group's initial focus is on "ANCA-associated" vasculitides of Wegener's granulomatosis (WG) and microscopic polyangiitis (MPA). During OMERACT 7 a research agenda and priorities for future work in this area were developed. The current state of disease assessment in vasculitis and the research agenda were presented by members of the group to other OMERACT 7 participants, and important feedback was received from experts experienced in disease assessment who are not involved in vasculitis research.

This article critically reviews the current status of tools for assessment of disease activity and damage and the current level of validation of each measure. In addition, central problems and controversies are addressed that need to be considered during the development of a new disease assessment tool in vasculitis.

Illustrative Case

A case summary from real clinical practice is presented to highlight the current state of, and challenges faced by, clinical assessment in WG and MPA:

A 53-year-old man with a 10 year history of WG returns for evaluation. His disease manifestations have included episcleritis, rhinitis, sinusitis, lung nodules and infiltrates, glomerulonephritis, and an upper eyelid mass. He was treated for a total of 36 months with cyclophosphamide, and extensively with glucorticoids. Current medications include prednisone (20 mg/day) and azathioprine (150 mg/day). Two years ago he was diagnosed with transitional-cell bladder carcinoma requiring cystectomy and an ileal conduit. One prior relapse was associated with lower extremity deep-vein thrombosis and pulmonary embolus. He has bilateral cataracts. When last seen, one month ago, he was well and reported only chronic non-bloody nasal crusting and discharge. He called for the present appointment because of a 3 week history of arthralgias, left eyelid and periorbital region pain and swelling, lacrimal gland enlargement, bloody nasal discharge, and maxillary region discomfort. Physical examination findings include periorbital edema, injected right conjunctiva, right lacrimal gland enlargement, right nasal cavity dry crusts, and fresh submucosal blood. Diagnostic studies reveal hematocrit 31%, white blood cell count 7570/ml, creatinine 1.8 mg/dl (increased from 1.4 the previous month), and erythrocyte sedimentation rate 40 mm/hour. Urine from the ileal conduit contains abundant debris and is positive for protein (1+), hemoglobin (1+), and red blood cell casts; the casts are a new finding. A chest computerized tomographic scan reveals areas of scarring from prior injury but is unchanged from previous study.

- What are the best approaches to evaluating this patient's disease course quantitatively?
- How to quantify his disease activity now?
- What was his disease state one month ago?
- What is his disease state now?
- How should his case be classified?
- How to quantify his level of disease-related damage now?

Introduction to Vasculitis Disease Assessment Tools

In patients with primary systemic vasculitides, assessment of response to therapy in clinical trials needs to include 3 distinct categories that can be influenced by an experimental treatment independently from each other: disease activity, disease damage, and function. Disease activity is defined as any clinical manifestation of the specific disease, such as glomerulonephritis, purpura, or fevers; disease activity needs to be distinguished from clinical comorbidities and treatment-related complications. In contrast, disease damage represents scars that resulted from previously active vasculitis, or from therapy. It is important, but often difficult, to differentiate disease activity from damage in vasculitis because both can be present simultaneously, even in the same organ system. Finally, changes in physical function and health-related quality of life may be a result of disease activity, disease damage, or comorbidities.

Due to the diversity of clinical manifestations present in patients with vasculitis, response to treatment cannot be judged by observation of a single clinical or laboratory measure or by functional assessment of a limited number of organs. With the goal of obtaining a single quantitative measure of disease activity or damage in patients with vasculitis, a number of compound indices have been developed by different investigators[1-7], which will be briefly reviewed. In general, each of these instruments requires a comprehensive assessment of disease status in all organs and summary scores arrived at after the weighting of single items.

Challenges and Controversies in Vasculitis Disease Assessment

The vasculitis research community faces several important challenges and controversies regarding the currently available disease assessment tools:

Multiplicity of instruments. The existence of different vasculitis disease assessment tools has led to problems comparing data across clinical trials and between cohorts. Further, while each features unique advantages for use in certain situations (e.g., clinical trial, longitudinal observational study, clinical practice), no tool is ideal for general use.

Disease-specific versus generic vasculitis instruments. While some manifestations of primary systemic vasculitis are common to many different vasculitides (e.g., polyneuropathy, purpura), other features are more or less specific for certain entities within the broad spectrum of vasculitic diseases (e.g., pulmonary nodules in WG, aortitis in large vessel vasculitis). Few manifestations are seen in all of the diseases.

The simplicity of using a single tool in all vasculitides is appealing. Alternatively, given the differences in disease spectrum, treatment, and prognosis across the vasculitides, disease-specific instruments may provide greater precision and focus for use in clinical trials.

While the single tool offers the advantage of systematically capturing all possible manifestations of vasculitis independent of the specific disease under study, some component items may never be used in clinical trials investigating one vasculitis subtype only (e.g., WG); moreover, a less common, but important feature of that disease may not be listed. Although more uncommon items may be scored under a free-text category "other," they may not be recognized by less experienced investigators if not separately listed and may not contribute to an active vasculitis score when they should. Conversely, listing all potential items of disease activity for all diseases would generate an impossibly long and unwieldy instrument.

The issue of disease-specific versus pan-vasculitis disease tools also arises when studying inflammatory arthritis. While rheumatoid arthritis, psoriatic arthritis, and juvenile rheumatoid arthritis share many features, these diseases have different enough features and prognosis to justify separate disease assessment tools, which have evolved for use in clinical trials.

The above arguments led to a revision of the original Birmingham Vasculitis Activity Score (BVAS)[1], a "generic" vasculitis disease assessment tool, and creation of a specific instrument for WG (BVAS/WG) for use in clinical trials involving patients with WG only[2]. However, not all research groups have adopted this new approach, resulting in further variability in the literature.

Given the well recognized advantages and disadvantages of the generic versus the specific approach, a modular disease activity index in vasculitis may constitute a promising compromise. In such a system, a "base" module would include manifestations common within this disease spectrum (e.g., arthritis, neuropathy, purpura); weighting and scoring of these "general" items would be the same regardless of disease under study. To this "base" module, a disease-specific module could be added that incorporates items specific for a given entity (e.g., nasal crusting in a WG-specific module, or eosinophilic pneumonia in a Churg-Strauss syndrome-specific module). This approach may lend itself well to MPA and WG, where there are both many overlapping and differing features[8-10]. Future work of this study group will focus on whether the concept of a disease-specific *and* modular approach is feasible and advantageous.

Nomenclature and classification of vasculitides and assessment instruments. The ongoing debates regarding diagnostic criteria, disease classification, and disease subclassification in clinical vasculitis are paralleled in the field of outcome measure development in vasculitis[11-13]. In particular, use of the terms ANCA-associated vasculitis (AAV) and ANCA-positive vasculitis (APV) to represent WG, microscopic polyangiitis, and sometimes, but not always, Churg-Strauss syndrome, are not uniformly applied or accepted. Marked similarities in disease presentation, prognosis, and treatment between WG and MPA make it attractive to link these 2 diseases for purposes of outcome assessment (they are increasingly studied in combination in clinical trials); however, such linkage remains controversial. Similarly, the treatment of Churg-Strauss syndrome differs enough from treatment of WG or MPA to exclude it from this initial series of projects. This issue of merging assessments of WG, MPA, and Churg Strauss syndrome, however, may be remedied by a modular approach to disease activity index design as discussed above.

Multiple uses of disease assessment tools: complexity versus feasibility. As they evolve, disease assessment tools in vasculitis increasingly serve to quantify disease activity and determine disease stratification, trial randomization, prognostication, and other uses. Their multiple uses, described in greater detail below, highlight the struggle between keeping an instrument simple yet comprehensive enough to provide detailed information on these complex diseases.

Differing disease-state definitions. Investigators have used different definitions of active disease, remission, and flare to describe patients in clinical trials of vasculitis. These differing disease-state definitions have led to problems in comparing efficacy of different therapeutic regimens, in applying results to clinical practice, and in developing outcomes tools and new trial designs.

Inadequacies of current instruments regarding scalability, weighting, comprehensiveness. The systems for weighting items and overall scaling for the current vasculitis outcome instruments were arrived at mostly through expert opinion rather than longitudinal data reflecting prognosis or resultant disability. The weighting systems are clearly problematic. Currently, the weights neither address the many gradations of specific disease manifestations, nor clearly reflect the degree of either biological or functional impact on patients. There is also a need for more patient input into the

process. Further, there are potential discrepancies between a patient's disease state and the corresponding score. For example, a patient with multiple "minor" disease items in WG may have a higher score, even with weighting, versus a patient with one major item such as alveolar hemorrhage; yet the latter patient is universally thought to be in a more severe disease state. These problems exist for measures of both disease activity and disease damage.

Acceptance by regulatory agencies and the pharmaceutical industry. It is essential that outcome tools for vasculitis be accepted by government drug-approval agencies and by the pharmaceutical industry. Feedback from the US Food and Drug Administration, the European Medicines Evaluation Agency, other similar bodies, and industry partners will be an important part of developing the next generation of outcome tools in vasculitis.

Philosophy of Disease Activity Assessment in Vasculitis

Measures of disease activity, extent, and severity are necessary now that markedly improved prognosis of systemic vasculitis means death is no longer the common endpoint. Physicians need to measure disease activity and morbidity in vasculitis patients in order to make therapeutic decisions, catalog disease manifestations, provide prognostic information, and compare different groups of patients. Measures of disease activity are also important in assessing response to treatment over time. This is particularly true for diseases in which remission may not be immediately achieved and in which relapses are common[14]. Recurrent exacerbations of vasculitis often lead to increased morbidity due to both the disease and its treatment. Therefore, the ability to define, quantify, and differentiate disease activity from irreversible damage is crucial to guide treatment and minimize treatment and disease-related morbidity.

Several indices have been developed to accurately measure disease activity in systemic vasculitis, for application in clinical trials and in clinical practice[1-6]. Some indices are designed to be comprehensive and can be applied to many forms of vasculitis (e.g., Birmingham Vasculitis Activity Score)[1], while others are disease-specific (e.g., the BVAS for WG[2]).

Desirable properties of a vasculitis disease activity tool are outlined in Table 1.

Table 1. Desirable properties of a vasculitis disease activity tool.

1. Ability to quantify disease activity on a continuous scale
2. Ability to quantify change in disease activity over both long and short time periods
3. Ability to determine disease states by distinguishing among:
a. High disease activity
b. Low disease activity
c. Remission
4. Ability to discriminate clinically relevant disease subsets with unique characteristics
5. Ability to provide prognostic information in regard to both morbidity and mortality
6. Feasibility for use in clinical trials
7. Feasibility for use in clinical practice
8. Simple, one-page format for use with paper-based or computer-based data entry

Summary of Vasculitis Disease Assessment Tools

The most commonly used indices in clinical practice and research settings are outlined in Table 2; copies of the instruments and instructions for use can be found at the VCRC website (http://rarediseasesnetwork.org/vcrc). All these tools share many features and serve to catalog manifestations of systemic vasculitis. BVAS/WG and BVAS 2003 are variations on the same theme, each having evolved from the original BVAS, but differ mainly in disease specificity versus generalizability, attention to persistent disease, and in the methods of item weighting and overall scoring. All 3 activity measures catalog disease manifestations grouped by organ systems, require investigators to determine whether a feature is due to active vasculitis in the past 28 days, and assign weights to different items that were empirically determined by expert opinion. The issue of differentiating persistent, or "grumbling," vasculitis activity from more clear-cut active disease is part of all 3 activity measures, but this item remains problematic and there is no consensus as to how to resolve the issue. Further, the instruments vary in the range of gradation of disease severity recorded. Additionally, all the measures have an open-text category "other," where items can be added for scoring individual patients. "Other" categories allow flexibility and accommodate unusual disease features (e.g., granulomatous breast mass), but also lead to inclusion of unstandardized items. All 3 tools include glossaries with item definitions; users are required to undergo training to learn the proper scoring technique.

The Disease Extent Index (DEI) provides information regarding the number of organ systems with active vasculitis (i.e., disease extent)[4,15]. Thus, the DEI has been used in clinical trials as an adjunct to the BVAS to provide information not contained in the BVAS score, specifically whether a certain BVAS score is due to activity in one major (low DEI) or several minor organs (high DEI).

The Five Factor Score (FFS) was designed as a prognostic tool for vasculitis assessment and not for serial measures of disease activity[7]. The instrument is simple to use and has been validated in several studies. The included items are all disease activity tools and their prognostic information can, therefore, be derived from the information obtained with the activity measures at any chosen "baseline."

Vasculitis Disease Activity Measures: VCRC-OMERACT Research Agenda

No current vasculitis disease measure meets all the desirable properties outlined in Table 1. Our overall goal is to devel-

Table 2. Vasculitis disease assessment tools.

Assessment Tool (year of developement/ release)	Validation*	Disease Assessment	Types of Vasculitis Tool Is Used For	No. of Organ Systems Evaluated	No. of Items	How Was Weighting Method Arrived at?	Remission Defined?	Training Required?	Comments
Activity Measures									
BVAS, 1997[1]	Complete	Activity (new/worse)	All	9	71	Consensus	Yes	Yes	1. Most widely used tool 2. Comprehensive organ system list
BVAS/WG, 2001[2]	Partial	Activity (new/worse)	WG MPA	9	35	Consensus	Yes	Yes	1. Useful evolution of original BVAS 2. Disease-specific
BVAS 2003, 2003	In progress	Activity	All	9	62	Consensus	Not yet	Yes	1. Incorporates changes in light of BVAS and BVAS/WG
DEI, 2001[4]	Partial	Extent	WG	11	11	Consensus	Yes	No	1. Similar approach to BVAS variants but less detailed 2. May be more valuable as prognostic than assessment tool
Prognostic Tool									
FFS, 1996[7]	Partial	Prognosis	PAN MPA CSS	4	6	None	NA	No	1. Extremely simple to complete 2. Purely used for prognosis
Damage Assessment									
VDI, 1998[5]	Complete	Damage	All	10	64	None	NA	Yes	1. Only damage index in use 2. No casual attribution 3. No scaling

* Per OMERACT filter of truth, discrimination, feasibility[23]; NA: not applicable; BVAS: Birmingham Vasculitis Activity Scale; BVAS/WG: BVAS for Wegener's Granulomatosus; DEI: Disease Extent Index; FFS: Five Factor Score; VDI: Vasculitis Damage Index.

op a single, consensus-approved, disease activity measure specific for WG and MPA (ANCA-associated vasculitis) for use in clinical trials that includes all those properties. Our objective is to improve upon the existing tools by extracting the most effective components or modifying existing tools to develop a more accurate vasculitis disease activity index. Although some expert opinion will drive the process, data-driven approaches will be used whenever possible. Sources of data appropriate for activity tool development include various clinical trial and longitudinal cohort databases available to the investigators, and prospectively collected data from both virtual patient evaluation exercises and clinical practice information. Validation of the newly created consensus instrument(s) and direct comparisons to current tools will be performed at multiple international centers.

A better understanding of the underlying pathogenesis of these diseases may lead to a markedly different approach to disease assessment. However, at present we are committed to improving existing tools and winning widespread acceptance of a single, data-derived, standard disease assessment tool.

Assessment of Illustrative Case: Disease Activity

Cataloging the above described patient's disease activity can be done by noting arthralgias, periorbital and lacrimal gland swelling, rhinitis, sinusitis, and nephritis. Some of the current tools directly collect most of these items, but no tool captures all the items well. More challenging is how to quantify his active disease burden to allow assessment of treatment efficacy and prediction of outcome. Further, assessment using each of the current instruments would identify subtle but distinct differences in this patient.

Definitions of Disease Status and Disease Classification in Vasculitis

Establishing well founded definitions of disease status is a cornerstone for accurately describing populations and outcomes for all types of clinical cohorts and therapeutic trials in vasculitis. Further, such definitions may serve as reference points to validate disease activity tools. Treatment may lead to patients with vasculitis achieving a state of clinical remission that may sometimes last even for long periods

after cessation of therapy. Nevertheless, disease relapse is common and can range from mild, perhaps necessitating only a small increase or additional dose of glucocorticoids, to a severe flare involving vital organs and causing life-threatening complications, requiring institutions of or escalation of high-dose glucocorticoids and cytotoxic therapy. Thus, any definition of disease state (a categorical measure of disease activity) and disease class (a categorical rating of disease that takes prognosis and response to treatment into consideration) must, at time of assessment, take into consideration: level of disease activity, current treatment, past disease manifestations, and transitions from one disease state to another. Finally, these definitions should both correlate with clinical practice and be useful for clinical trial outcome assessment and subject stratification.

Significant differences in defining disease status for patients with WG and MPA exist among investigators, leading to problems when comparing study results. For example, the definition of "remission" in a recent European trial allowed for use of low-dose glucocorticoids, while the definition in a recent US trial reserved the term mostly for patients completely off glucocorticoids[16,17]. Multiple definitions exist for complete or partial remission and persistent, active, limited, or severe disease states[18-20], yet these terms do not cover all disease states patients present during a trial. Further, the definitions are not all precise and were not arrived at by data-driven processes.

Classification (stratification) of patients by disease severity has important implications for prognosis and therapeutic decision-making. Thus, it is critical to use such definitions when describing patient populations and designing clinical trials. Disease classification in WG and MPA is hampered by multiple systems of nomenclature, each derived by expert opinion and not more comprehensive data validation. Early definitions of limited WG do not correlate with later ones. The EUVAS group defines 5 disease strata in vasculitis: localized, early systemic, generalized, severe renal, and refractory[19], while the WGET (US) group defined 2 states: limited and severe[20].

Vasculitis Disease States and Classes: VCRC-OMERACT Research Agenda

As outlined above, there is currently no consensus on how disease status should be defined for vasculitis, or which terms should be used, particularly for WG and MPA. The VCRC-OMERACT group had extensive discussions about disease status and classification and have agreed to a comprehensive research agenda that seeks to generate international consensus and to achieve data-driven improvements in these outcome measures.

We propose to first derive operational definitions of 3 disease states: high disease activity, low disease activity, and remission. The 3 states may be qualified by the 2 conditions "on treatment" or "off treatment," which must be clearly defined in terms of glucocorticoid and other treatments. Further, difficult issues need to be addressed regarding the concept of persistent disease. Finally, time elements for the disease states need to be clearly defined.

These definitions will be derived both by consensus opinion and by reference to available datasets from US and European clinical trials. The utility and validity of disease states will be determined through analysis of clinical trial data and performance of validation exercises with multiple international investigators in actual practice.

Similar approaches will be used in drafting consensus definitions and validating final versions of disease classifications for WG and MPA. Further, any resulting consensus definitions of disease states and strata for WG and MPA must be fully compatible with the new disease activity and damage assessment tools being developed.

Assessment of Illustrative Case: Disease State and Classification

What was this patient's disease state one month ago? Could he be considered in remission although still taking prednisone 20 mg daily?

What is his current disease state? High disease or low disease state?

What will it take to deem him in remission?

What effect do chronic nasal and sinus problems have on such decisions?

What is his disease class? Limited or severe? Do we determine classification based on past or current manifestations?

Assessment of Damage in Vasculitis: Introduction

Clinical trials frequently focus on the concept of disease activity. However, for some patients, especially after the initial flare has been treated, the most troublesome issue may be disease damage. Although the concept of damage seems intuitive, it must be strictly defined to ensure reproducibility among clinicians and between studies. It is essential to differentiate damage from active disease, although this can be difficult. Additionally, attribution of damage to vasculitis, treatment, or other medical problems can also be challenging.

The Vasculitis Damage Index (VDI) was introduced in 1997 as a generic measure of vasculitis damage and is the only tool for damage assessment used on a regular basis[5]. The VDI comprises 64 items of damage, grouped into 11 organ-based systems. Damage is defined in the VDI as irreversible pathology lasting longer than 3 months, a time period chosen to help ensure that reversible problems were not counted as damage.

Application of the VDI has yielded several important lessons: (1) Accumulation of damage appears to be bimodal, with an earlier phase due to the vasculitis itself, and a later phase likely due to therapy[21]; (2) early damage is predictive of mortality[21]; (3) fatal vasculitis is characterized by higher

total VDI scores affecting a greater number of systems than nonfatal vasculitis[22].

A modified version of the VDI, incorporating slightly different time periods and dropping a few items, was used in a recent multicenter trial[17], thus adding to the variation in vasculitis disease assessment in the literature.

Challenges and Controversies in Vasculitis Damage Assessment

The purpose of a damage index for vasculitis is 3-fold: (1) to serve as an outcome for clinical trials; (2) to record the natural history of treated disease; and (3) to better define the difference between activity and damage. Any reexamination of the measurement of damage in vasculitis must address how we may better accomplish these goals. Further, the definition of damage used by the VDI[5], while ostensibly straightforward, makes several assumptions, each of which affects the tool's utility and several of which are controversial.

Irreversibility. Items of damage in the VDI are, by definition, irreversible; yet some features of disease, such as peripheral neuropathy, reverse although it may take months or years to resolve.

Time element. Three months is the period of time an item must be present to be considered damage; this was somewhat arbitrary and should be reassessed in a data-driven exercise.

Attribution. The VDI does not require any assessment of damage etiology. The VCRC-OMERACT group wishes to investigate the usefulness and feasibility of attributing damage to vasculitis, treatment, or other medical comorbidities.

Weighting and grading. Each item of damage in the VDI is given equal weight (one point), yet that clearly does not reflect the relative severity of damage incurred. For example, oxygen-dependent pulmonary disease or blindness must be weighed differently than a healed pulmonary nodule or partial quadrant visual loss. Finer gradations of damage may also be needed to, for example, differentiate mild renal insufficiency from endstage renal disease necessitating dialysis.

Patient-derived assessment. It may be necessary to take into greater consideration patients' self-assessment of the consequence of damage, either by incorporating patient self-assessments and/or including patients in the drafting of new damage assessment tools.

Generic versus disease specificity. The VDI aims to measure damage in all forms of vasculitis. However, regarding disease activity, there are advantages to developing specific tools for assessing damage in the individual vasculitides.

Vasculitis Damage Assessment: VCRC-OMERACT Research Agenda

The VCRC-OMERACT group is pursuing the development of a new damage assessment tool specific for WG and MPA. This process will include comprehensive data collection in the context of a multicenter clinical trial as well as international practice sites. The new tool incorporates some of the concepts in the VDI, but will also address each of the challenges raised above. Validation of any new instrument will include comparison with the VDI and use of longitudinal data.

Assessment of Illustrative Case: Disease Damage

This patient has suffered considerable damage as a result of his WG and the treatments he has received. Which of his many problems should be considered damage? What relative weights should be given to his upper airway problems versus his ileal conduit versus his cataracts? What if his cataracts are corrected by surgery? Is it useful to differentiate the damage from WG (e.g., sinus) from that from treatment (e.g., bladder carcinoma)?

Summary

The complexity of assessing disease activity, disease status, and damage in the vasculitides reflects the multisystemic pathologic manifestations of these often chronic illnesses, and many groups of investigators have been confronted with this challenge. The VCRC-OMERACT group is optimistic that by combining our collective expertise, resources, data, and experience, we will help advance the science of disease assessment in vasculitis and create widely accepted and utilized outcome measures for clinical investigation into these serious diseases.

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Articles presented at OMERACT 7 Conference
Asilomar, California, May 8–12, 2004

Modules
- Minimal Disease Activity for RA
- OMERACT Working Group on Safety
- Ankylosing Spondylitis: Imaging

Workshops
- Patient Perspectives in Outcome Measurement
- Outcome Measures in Psoriatic Arthritis
- Outcome Measures in Fibromyalgia Syndrome

Special Interest Groups
- Concomitant Therapies
- Gout
- Measurement of Erosion Size/JSN
- Magnetic Resonance Imaging
- Psycoeducational Self-Management Interventions
- Reconciling Subject Differences in RCT
- Synovial Tissue
- Ultrasound Imaging
- Vasculitis

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