Introduction.— Assessment of disease activity in large vessel vasculitis (LVV) is challenging. To develop well-accepted and validated outcome measures for use in clinical research in LVV, a Delphi exercise has been launched as part of an international initiative to systemically arrive at consensus expert opinion and identify candidate outcomes for assessment of disease activity in LVV.

Methods.— The Delphi survey was sent to > 300 experts in LVV from different specialties. The first round included 99 items on a 5-point scale aiming to cover potential disease manifestations. Items accepted or rejected by > 70% of voters are not advanced to subsequent rounds.

Results.— One hundred and sixteen experts from 23 countries completed the survey. Most vascular/cardiovascular items were accepted by > 70% of experts for Takayasu’s (TAK); ocular findings were considered high-priority outcomes for GCA. Vascular imaging was accepted for both TAK and giant cell arteritis (GCA). SF36 and patient global assessment were widely accepted in both diseases. DEI. Tak was the only composite index accepted for TAK. Only ESR and CRP were suggested as biomarkers in TAK; hemoglobin level was also supported in GCA. Findings rejected by > 70% of the experts included erythema nodosum for TAK and pulmonary assessments for GCA. Additional items proposed by participants (e.g. IL-6 levels and novel PRO measures), and the items that did not reach the 70% threshold, will be considered in subsequent rounds. 63% of experts voted to have a common approach for both TAK and GCA but to also develop additional specific instruments for each disease; 25% felt the two diseases were unsuitable for common outcome measures.

Discussion.— This exercise points out to similarities and differences from experts’ perspective for assessing the clinical activity in TAK and GCA.

Conclusion.— Based on the Delphi, it is anticipated that a consensus-driven set of outcomes will include many data elements common to both diseases, supplemented by disease-specific items for TAK and GCA.

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Factors associated with major cardiovascular events in patients with primary systemic necrotizing vasculitides: Results of a longitudinal long-term follow-up study

B. Terrier1, C. Pagnoux1, G. Chironi2, A. Simon2, L. Mouton1, L. Guillemin1

1. Cochin, Paris, France
2. HEGP, Paris, France

Introduction.— Primary systemic necrotizing vasculitides (SNV) were shown to be associated with more frequent subclinical atherosclerosis, independently of cardiovascular (CV) risk factors and C-reactive protein (CRP) level, suggesting that SNV might be associated with a higher risk of major CV events (MCVE).

Objective.— To identify factors predictive of MCVE in SNV patients.

Methods.— Consecutive patients in SNV remission were assessed for CV risk factors and subclinical atherosclerosis, and prospectively followed in the same center. High-risk status, defined according to the NCEP/ATP III, was a known history of CV disease, diabetes or 10-yr Framingham Risk Score ≥ 20%. MCVE, defined as myocardial infarction, stroke, arterial revascularization, hospitalization for unstable angina and/or death from CV causes, were recorded. Kaplan–Meier MCVE-free survival curves were plotted and compared with the log-rank test.

Results.— Thirty-seven patients (24 males, age 54 ± 15 yr) were followed for 7.0 ± 2.6 yr. SNV diagnoses were: GPA, 19; EGPA, eight; MPA, seven; and PAN, three. Seven (18.9%) patients suffered MCVE. The respective 5- and 10-yr MCVE rates were 10.8% and 25.7%.

Univariate analysis selected NCEP/ATP III-defined high-risk status (HR 5.02, P = 0.03), BMI ≥ 30 kg/m² (HR 4.84, P = 0.02) and plaque