

REFERENCE:

- [1] Zouboulis C., Vaiopoulos G., Macromichelakis N. et al. Onset signs, clinical course, prognosis, treatment and outcome of adult patients with Adamantiades – Behçet's disease in Greece. *Clin.Exp.Rheum.*2003, 21, (suppl.30) S19-S26.

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THU0303 THE OMERACT CORE DOMAIN SET FOR CLINICAL TRIALS IN BEHÇET'S SYNDROME

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Background: There is an unmet need for reliable, validated, and widely-accepted outcome measures for clinical trials in Behçet's syndrome (BS).

Objectives: The Outcome Measures in Rheumatology Clinical Trials (OMERACT) Behçet's Syndrome Working Group has worked to advance the creation of a data-driven Core Domain Set for use in all clinical trials.

Methods: The Core Domain Set was developed through a comprehensive, iterative, multi-stage, multi-year project that followed the methodologically rigorous processes and standards set forth by OMERACT: i) a systematic review; ii) a survey among experts in BS; iii) an outcome measures interest group meeting during the International Conference on Behçet's Disease; iv) qualitative patient interviews; v) a three-round modified Delphi exercise involving both patients with BS and a multidisciplinary set of physicians expert in BS, focused on obtaining consensus on the domains of illness necessary in the study of BS; and vi) utilization of the data, insight, and feedback generated by the outlined processes to develop a final Core Domain Set. The final Core Set was presented and put up for a vote of endorsement at the 2018 OMERACT meeting.

Results: All steps in the processes outlined were completed. The systematic review clearly demonstrated the substantial variability in the domains studied in clinical trials of BS and a lack availability of validated outcome measures in BS. The survey of physicians, the in-person meeting of experts, and the qualitative research with patients all helped generate an extensive list of candidate domains and sub-domains to consider for use in clinical trials. It also became clear that there was a need and strong interest in delineating domains across the several major organ systems involved in this disease and in recognizing that clinical trials in BS often focus on specific manifestations and not the disease in its entirety. The Delphi involved 74 physicians expert in BS from 21 countries and from a wide range of specialties, and 64 patients from 10 countries. The Delphi utilized both ratings and rankings to prioritize the 56 domains and sub-domains originally under consideration.

The final proposed Core Set included 5 sub-domains mandatory for study in all trials in BS, with additional sub-domains mandatory for study of specific organ-systems when that system is the focus of a trial: mucocutaneous (2 additional sub-domains), ocular (4), central nervous system (3), musculoskeletal (2), vascular (4), and gastrointestinal (2). The final Core Set was strongly endorsed at the 2018 OMERACT meeting.

Conclusion: Multiple disease-related domains in BS have been identified by physicians and patients as important to address in clinical trials, leading to the development and endorsement of a final Core Set of Domains for use in clinical trials in BS. The Core Set provides the foundation through which the international research community, including clinical investigators, patients, the biopharmaceutical industry, and government regulatory bodies can harmonize the study of this complex disease, compare findings across studies, and advance development of effective agents.

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Sanofi, Employee of: Samumed, LLC, Peter Tugwell: None declared, Hasan Yazici: None declared, Peter Merkel: None declared
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THU0304 PREVALENCE AND MANAGEMENT OF CARDIOVASCULAR RISK FACTORS IN ANCA-ASSOCIATED VASCULITIS: A CROSS-SECTIONAL STUDY IN THE NETHERLANDS AND CANADA

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Background: Patients with ANCA-associated vasculitis (AAV) are at increased risk of cardiovascular (CV) disease.(1)

Objectives: The aim of the present study was to determine the prevalence of CV risk factors in patients with AAV and to evaluate the management of CV risk factors according to current guidelines.

Methods: A cross-sectional study was performed in patients with AAV in the Netherlands and Canada. Information on traditional CV risk factors, as well as markers of inflammation and kidney function, were collected. Their prevalence and treatment were studied and compared with recommendations in current guidelines.

Results: A total of 144 consecutive patients with AAV were included (71 from the Netherlands; 73 from Canada). Mean age was 62 ± 15 years, and 56% were male. The mean disease duration was 7.0 ± 6.6 years; 69% had granulomatosis with polyangiitis, 17% microscopic polyangiitis and 14% eosinophilic granulomatosis with polyangiitis. Mean body mass index was 28 ± 6 kg/m² and 65 patients (45%) had an estimated glomerular filtration rate <60 ml/min. The mean C-reactive protein was 6.5 ± 12.3 mg/l. Dyslipidemia was present in 69% and hypertension in 72%. In 36% and 25% of the included patients, blood pressure and dyslipidemia, respectively, were not managed in accordance with national guidelines.

Conclusion: Patients with AAV have a high prevalence of traditional CV risk factors. Whether past or persistent inflammation and chronic kidney disease further increases the CV risk remains to be studied. Strict adherence to CV risk management guidelines should be encouraged.

REFERENCE:

- [1] Houben E, Penne EL, Voskuyl AE, van der Heijden JW, Otten RHJ, Boers M, et al. Cardiovascular events in anti-neutrophil cytoplasmic antibody-associated vasculitis: a meta-analysis of observational studies. *Rheumatology (Oxford)* 2018; 57: 555-62.

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THU0305 ABSTRACT WITHDRAWN

THU0306 NEUTROPHIL ADHESION MOLECULES AND INFLAMMATORY CYTOKINES AS BIOMARKERS FOR MONITORING DISEASE PROGRESSION IN GIANT CELL ARTERITIS

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Background: Monitoring giant cell arteritis (GCA) activity with appropriate biomarkers is important, as current evaluation, based mainly on clinical symptoms/signs and traditional markers of inflammation, is not always sufficient and reliable.

Objectives: Our goal was to identify cellular and molecular biomarkers that could help clinicians to closely monitor GCA progression and/or treatment response.

Methods: Peripheral blood was obtained from 27 GCA patients at time of diagnosis (before glucocorticoid (GC) treatment), and subsequently at