Abstract SP0125 – Table 1. Clinical features of some forms of systemic vasculitis

Type of vasculitis	Systemic	Eye	Skin	ENT	Lung	Heart	Gut	Renal	PNS	CNS
Takayasu arteritis	<65%	30%	3-28%	-	50-86%	5-55%	7-9%	0-50%	-	33%
Giant cell arteritis	40%	20-50%	<5%	<50%	<10%	10%	-	-	14%	0-90%
Polyarteritis nodosa	<66%	10-20%	8-27%	-	-	10-40%	40-60%	30-50%	50-75%	1%
Granulomatosis with polyangiitis	30-97%	28-58%	10-50%	75-98%	52-94%	0-12%	5-11%	40-100%	15-41%	6-13%
Microscopic polyangiitis	73-92%	28-30%	35-60%	20-30%	25-55%	9-18%	30-56%	up to 100%	14-58%	0-40%
Eosinophilic granulomatosis with polyangiitis	69-100%	10%	51-69%	0-80%	100%	28-49%	8-59%	16-27%	65-76%	9-11%

individual forms of vasculitis, but it is important to remember that many features associated with medication and co-morbidity may make this patient group more homogeneous, especially if the original disease manifestations are now quiescent.

We will explore the potential use of classification criteria as substitutes for diagnostic criteria in different forms of vasculitis and evaluate the role of specific tests to assist in the diagnosis, with a focus on ANCA testing in small vessel vasculitis and on imaging in large vessel vasculitis.

Conclusion: A rational approach to diagnosis in vasculitis is required, based on a combination of clinical features together with relevant investigations. Diagnostic certainty can vary in the absence of definitive evidence from investigations, especially if patients have already been partly treated prior to completing all relevant investigations. Diagnostic testing is improving and with the development of new criteria for classification, this forms a stronger basis to develop a more sound approach to diagnosis. However, we should always be prepared to apply a provisional diagnosis and reconsider any emerging evidence to suggest an alternative condition.

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SP0126 CLINICAL IMPORTANCE OF ANA ANTI-DFS70 ANTIBODIES

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Background: Analysis of anti-nuclear antibodies (ANA) is a hallmark in the classification criteria for many systemic rheumatic diseases, including systemic lupus erythematosus (SLE). ANA investigations performed with indirect immune fluorescence (IF) on HEp-2 cells detect autoantibodies against a large number of nuclear autoantigens, and is often followed by, or done in parallel to, investigations which determine the autoantibody specificities causing the IF ANA staining. Two IF ANA-associated SLE-specific autoantibodies, anti-double stranded DNA and anti-Sm, are included both in previous as well as emerging SLE classification criteria. But IF ANA itself is also included in all of these classification criteria (1-3). This is because a positive IF-ANA is regarded as an independent risk factor for SLE, irrespective of what autoantibody specificity determines the nuclear staining. Antibodies against lens epithelium-derived growth factor 70/75 kD autoantigen creates a specific dense fine speckled IF-ANA pattern, and the autoantibodies are generally called anti-DFS70. The rather recently described anti-DFS70 pattern is unique and has obtained the AC-2 pattern in the recent universally accepted International Consensus on ANA Patterns (ICAP) classification system (www.anapatterns.com), but was not previously recognised and might be misinterpreted. In

contrary to other IF-ANA patterns/specificities, isolated anti-DFS70 is not associated with systemic rheumatic diseases, and might even be more common among healthy individuals than among diseased populations (4). However, when anti-DFS70 occur together with other ANA specificities, different IF-ANA patterns may predominate.

Objectives: The European Consensus Finding Study Group on autoantibodies (ECFSG), a.k.a. the EULAR autoantibody study group, regularly investigate autoantibody content in new autoantibody reference standards produced to obtain consistent results between clinical laboratories.

Methods: In the 2018 ECFSG serum investigation, a newly produced pooled anti-DFS70 reference standard was investigated blindly concerning IF ANA patterns and autoantibody specificities by 38 participating laboratories.

Results: Most laboratories correctly described the IF-ANA pattern correctly as the dense fine speckled AC-2 pattern; however 5/38 laboratories reported the pattern as homogenous (AC-1). Concerning autoantibody specificities, the standard was determined to be monospecific for anti-DFS70. This new reference standard has recently been described (5), and will be available via www.autoab.org.

Conclusion: In my talk I will give a background on the emergence of anti-DFS70 antibodies, and report on the outcome of the ECFSG investigation of the anti-DFS70 reference standard. Moreover, I will present an algorithm for how to incorporate investigations for anti-DFS70 in ANA investigations in a cost efficient way.

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FRIDAY, 14 JUNE 2019

13:30:00 – 15:00:00

The benefits of involving patients in health technology assessment

SP0127 PATIENT ENGAGEMENT WITHIN THE EUROPEAN MEDICINES AGENCY

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The European Medicines Agency (EMA) is the European regulatory body whose role is to evaluate and supervise medicines across the European Union.

EMA has been engaging with patients and consumers for many years and today, patient involvement is an integral part of the work at EMA, with a diverse range of opportunities in place to include the patient's voice at various stages along the medicines regulatory life-cycle. Key to successful engagement has been the need for flexibility, a range of well-tested methodologies and a robust system of support and training.

Patients and caregivers' real-life perspectives and unique insights complement the scientific data within EMA reviews; they provide input on proposed protocol designs and participate in expert meetings and written consultations on medicines evaluation. They are voting members of EMA committees and they review medical information written for the public. Evidence has shown their contributions make a difference and ultimately help ensure that the Agency's outcomes are as meaningful and relevant as possible for all concerned.

Some of the key challenges and conclusions of our journey will be highlighted to serve as a guide to those considering a similar, rewarding path.

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