Article	Patient demographics	Main diagnosis	Serum CA-125 (U/mL)	Other tumour markers	Presence of effusions
Tong et al. (2017)	43 F	IgG4-RD	↑ (1065)	CA 19-9 ↑, AFP ↑, CEA ↔	Ascites, pleural and pericardial effusions
Khosla et al. (2016)	72 M	AIP	↑ (196.4)	CA 19-9 ↔, CEA ↔	N/A
Thomas et al. (2015)	46 F	AIH, AI myositis	↑ (417)	CA 19-9 ↑	Ascites
Zhou, Zeng (2014)	24 F	IgG4-RD (lung)	↔	CA 19-9 ↔, CEA ↔, CA-153 ↔	Pleural effusion
Fengqing et al. (2014)	Cohort study of 22 patients	IgG4-RD	↑ in 12/22	CA 19-9 ↑ in 6/22	N/A
Cheng et al. (2013)	45 M	AIP	↑ (77.5)	CA 19-9 ↔	Ascites, pleural effusions
Liu et al. (2012)	41 M	IgG4-RD (lung)	↔	CA 19-9 ↔, CEA ↔, PSA ↔, NSE ↔	No
Graham, Harvin (2016)	66 F	IgG4-RD (SM)	↔	CA 19-9 ↔, CEA ↔	Ascites
Ghadir et al. (2012)	70 M	AIP	↔	CA 19-9 ↔, CEA ↔	N/A
Dogaru et al. (2015)	60 F	SM	↑ (295.5)	CA 19-9 ↔, AFP ↔, CEA ↔	N/A
Buyukbayrak et al. (2011)	38 F	SM	↑ (44.5)	CA 19-9 ↔, AFP ↔, CEA ↔, CA 153 ↔	Ascites
Malter et al. (2017)	57 F	MP	↑ (630)	N/A	Ascites
Xiaoting et al. (2017)	Retrospective study of 7 patients (3 F, 4 M)	IgG4-RD (lung)	↑ in 3/3 F (46.54, 156, 85.58)	CA 19-9 and CEA ↑ in 1/3 F	No
			↔ in 4/4 M	CEA ↑ in 1/4 M	Pleural effusion in 1/4 M
Current report	56 M	IgG4-related MP	↑ (1358)	CA 19-9 ↔, AFP ↔, CEA ↔	Ascites

Abstract AB1369 – Figure 1

AI: *Autoimmune, AIH: Autoimmune Hepatitis, AIP: Autoimmune Pancreatitis, SM: Sclerosing Mesenteritis, ↑: Raised, ↔: Normal*

Conclusions: To our knowledge, this is the first SLR exploring the association between CA-125 and IgG4-RD and MP. Despite the small sample, our results do indicate that CA-125 was raised in more than 50% of reported cases, the majority of which also had some kind of effusion. Although traditionally a marker of ovarian cancer, this report highlights that a raised CA-125 can be found in other, non-malignant, inflammatory conditions, and potentially correlates with inflammatory burden. CA-125 in this setting may thus represent a useful biomarker and have a role in monitoring treatment response.

REFERENCE:

[1] Minato H, Shimizu J, Arano Y, et al. IgG4-related sclerosing mesenteritis: a rare mesenteric disease of unknown etiology. Pathol Int. 2012;62:281–6.

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AB1370 PATIENT REPORTED OUTCOMES MEASURESFOR FIBROMYALGIA: A REVIEW

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Background: Persons with fibromyalgia (FM) suffer from numerous symptoms with various levels of intensity, such as widespread pain, fatigue, cognitive dysfunction, non-restorative sleep, depression, and anxiety among others. The patient's perspective has been recognised by Outcome Measure in Rheumatology (OMERACT) as a key assessment in FM. For that reason, some patient reported outcomes measures (PROMs) have been developed. PROMs allow the comparison of a specific component of the disease in a patient through time, and also provide the opportunity to health professionals to compare patients between them in clinical trials. However, some PROMs are used over others despite a limited validation process. In addition, different versions of the same PROMs can coexist, what can lead to uncertainty when selecting the adequate instrument.

Objectives: To identify the existing PROMs for FM and analyse their psychometric properties.

Methods: The authors performed a comprehensive search in electronic databases (Medline, Embase, and Cochrane) in order to identify validation studies of PROMs for FM. Studies published between January 1990 and November 2017 were included. Generic PROMs and validation of diagnostic criteria and related screening tools were not considered as PROMs and were excluded. Information was gathered based on the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) checklist manual.

Results: The electronic search produced 1832 records. After screening, a total of 48 studies containing 16 PROMs for FM were included. The PROMs included address different constructs of the disease, Fibromyalgia Impact Questionnaire (FIQ), Revised Fibromyalgia Impact Questionnaire (FIQR), Combined Index of Symptom Severity, Combined Index of Severity of Fibromyalgia, Comprehensive Rating Scale for Fibromyalgia Symptomatology, Fibromyalgia Assessment Status, Fibromyalgia Bladder Index, Fibromyalgia Burden Assessment, Fibromyalgia Health Assessment Questionnaire, Fibromyalgia Impact Questionnaire+Visual Analogue Scales, Fibromyalgia Participation Questionnaire, Fibromyalgia Sleep Diary, Multidimensional Inventory of Subjective Cognitive Impairment, Multidimensional Patient Reported Outcome Measures Questionnaire, PROMIS Fatigue FM Profile, and Multidimensional daily diary of fatigue-fibromyalgia-17 items. Almost all PROMs have adequate content validity. Three PROMs do not report construct validity; seven do not report reliability, and six do not report internal consistency. Only three PROMs evaluate criterion validity and three responsiveness. The FIQ and the FIQR are the PROMs more widely cross-cultural validated with 18 and 13 adaptations respectively.

Conclusions: PROMs for FM have, in general, only partial validation of their psychometric properties. Validation of an instrument is a continuous process in which quality is more important than quantity. Instead of creating new PROMs for FM, future works should focus on completing missing parts of the validation process of existing ones. In addition, cultural adaptations and translations of the available PROMs should be prioritised in order to offer researchers across the globe a toolbox of options in where they can choose the best PROMs to address their objectives in a highly subjective syndrome as FM.

Disclosure of Interest: None declared
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AB1371 CLINICAL SIGNIFICANCE OF KL-6 AND SP-D AS SERUM MARKERS FOR INTERSTITIAL LUNG DISEASE IN PATIENTS WITH CONNECTIVE TISSUE DISEASE

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Objectives: To evaluate the association between serum levels of Krebs von den Lungen-6 (KL-6) and surfactant protein-D (SP-D) and the clinical manifestations and severity of interstitial lung disease (ILD) in patients with connective tissue disease (CTD).

Methods: Eighty patients with various CTDs were included, as follows: 33 with rheumatoid arthritis (RA), 19 with systemic lupus erythematosus (SLE), 10 with systemic sclerosis (SSc), 9 with Sjogren's syndrome (SS), and 9 with inflammatory myositis. KL-6 and SP-D levels were measured using an enzyme-linked immunosorbent assay and defined as abnormal if KL-6 $\geq$500 U/mL and SP-D $\geq$110 mg/mL. All patients were simultaneously evaluated for parameters related to disease activity using laboratory tests and a pulmonary function test, and interstitial lung abnormalities (ILA) using chest computed tomography (CT). Patients were subclassified according to ILA score: 0 for no ILD, 1 for indeterminate ILD, 2 for mild ILD, and 3 for advanced ILD based on chest CT scans.

Results: In all, 29 patients had radiologically advanced ILD, 18 had mild ILD, 18 had indeterminate ILD, and 15 had no ILD. A higher ILA score was associated with more severe dyspnea, and decreased volume and percent of functional vital capacity, forced expiratory volume in 1 s, and diffusion capacity of carbon monoxide. As clinical manifestations, a higher ILA score was associated with a higher GAP index but not with the parameters of disease activity. A higher ILA score was associated with higher levels of KL-6 and SP-D and a higher percentage of subjects with abnormal levels, and this was more pronounced in SLE, SSc, and SS than in RA.

Conclusions: Serum levels of KL-6 and SP-D are associated with the radiological severity of ILD. Hence, these can serve as markers for ILD severity, especially in SLE, SSc, and SS.

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AB1372 TOWARDS REFORMING THE TAXONOMY OF HUMAN DISEASE: THE PRECISESADS CROSS SECTIONAL STUDY

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Objectives: The PRECISESADS project aims at using OMICs, and bioinformatics to identify new classifications for systemic autoimmune diseases (SADs) known to share common pathophysiological mechanisms in view of personalised treatments. Multi OMICs parameters collected in addition to routine clinical data in a cross-sectional study involving patients suffering from systemic lupus erythematosus (SLE), systemic sclerosis (SSc), Sjögren's syndrome (Sjs), rheumatoid arthritis (RA), primary antiphospholipid syndrome (PAPs), mixed connective

tissue disease (MCTD), undifferentiated connective tissue disease (UCTD) and healthy controls (HC) will be analysed to identify clinically relevant clusters.
Methods: A European multi centre, non-randomised, cross-sectional clinical study was conducted in 18 sites and 9 countries. Collection of OMIC data including genetic, epigenomic, transcriptomic (from peripheral blood and from isolated cells), flow cytometry, metabolomics and proteomic in plasma and urine, exosome analysis and classical serology (antibodies and autoantibodies) was organised. Novel and innovative methodologies including fine flow cytometry were conducted. Quality procedures were established to ensure standardisation of samples collection, processing, transportation and storage. Techniques were validated to ensure reproducibility of analyses. Unsupervised bioinformatics and biostatistics approaches will be applied.
Results: Recruitment started in December 2014 and ended in October 2017. A total of 2656 participants were recruited: 377 RA, 470 SLE, 402 SSc, 385 SjS, 99 MTCD, 106 PAPs, 166 UCTD patients and 651 HCs. Median age was between 46 and 59 years and was consistent with each disease onset peak. 97% of the population was Caucasian. Most of the patients were treated with standard of care therapies and less than 10% were on biologics. OMICs and bioinformatics analyses are on-going.
Conclusions: We have established one of the largest collaborative multi-OMICs studies from patients with SADs. The most important challenge is now the integration of all these novel data to support hypothesis-free, machine learning-led analytical protocols. It is expected that the integration of data from affected patients, in comparison with well-matched controls, will provide new biomarker-led descriptions of clusters of potentially etiologically distinct disease entities.
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AB1373 URINARY PROTEIN PROFILE COMPARISON BETWEEN SLE PATIENTS WITH AND WITHOUT RENAL INVOLVEMENT

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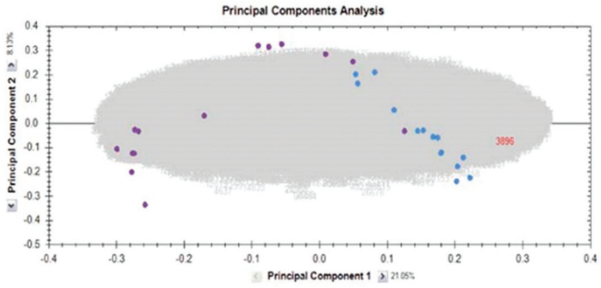
Background: Lupus nephropathy (NL) is an important cause of morbidity and mortality in patients with Systemic Lupus Erythematosus (SLE). The objective of the renal biopsy is to determine the type of glomerulonephritis that the patient presents to direct treatment. Considering that it is a specialised technique and not risk free, a proteomics study is proposed to determine biomarkers that help us to differentiate patients diagnosed with SLE with and without renal involvement.
Objectives: To determine if there is a different pattern of proteins between patients diagnosed with SLE with and without renal involvement.
Methods: We selected 12 patients diagnosed with SLE with renal involvement and 14 patients diagnosed with SLE without renal involvement. There were no differences between groups according to race, gener and age. The patients were classified as high, low or negative level of proteinuria in the urine. A 24 hour urine sample was obtained for analysis.
Results: We have done a Principal Component Analysis (PCA) where we can see differences between samples from patients who have high level of proteinuria in 24 hours and patients who have not renal involvement. Patients with positive proteinuria but not high level are a little confuse figure 1.
A total of 292 proteins (identified with at least two peptides with a FDR<1%) were quantified and further considered in the analysis. The Student's T-test analysis reflected the differential presence of 147 proteins (p<0.01). Of these, 130 were less abundant in the urine of the patients with renal damage, whereas 17 showed the opposite pattern, being more abundant in the patients with affected renal function.
Consistent with the nature of the sample, the Gene Ontology (GO analysis) of the whole list of identified proteins revealed the presence of extracellular (277 proteins, p=2.25E-171) and secretion-related proteins (49 proteins, p=1.1E-09), among others. Proteins related to defensive processes were prominent among them. Interestingly, the subset of proteins whose abundance increases upon renal damage is comprised of typical highly-abundant serum proteins. These proteins render a large number of peptides, suggesting they are very abundant. This protein pattern may reflect the higher albuminuria characteristic of patients with affected renal function. On the other hand, a number of proteins became significantly less abundant upon renal damage. The presence of highly abundant serum proteins in the urine of patients with compromised renal function may explain this phenomenon, since this will provoke a dramatic reduction in the relative abundance of the proteins already present in their urine.



Abstract AB1373 – Figure 1

Conclusions: A different protein pattern is observed between the two groups of patients, so in a more detailed study we can indicate if some of these can serve as prognostic markers for this type of patients.
Disclosure of Interest: None declared
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AB1374 PERFORMANCE OF EQ-5D, RAPID-3 AND HADS SCALES IN THE ASSESSMENT OF QUALITY OF LIFE AND FUNCTIONAL STATUS IN PATIENTS WITH ERYTHEMA NODOSUM

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Background: Erythema nodosum (EN) is the typical example of a mostly *septal panniculitis* with no vasculitis. Sarcoidosis and streptococcal infection are considered to be the most common etiological factors. There are no special scales available for practitioners to assess the efficacy of EN treatment in spite of high disease prevalence in general population. Sensitivity, specificity and validity of EQ-5D, RAPID-3 and HADS questionnaires have been demonstrated in other rheumatic diseases.
Objectives: The aim of this study is to evaluate the psychometric properties of EQ-5D, RAPID-3 and HADS scales in EN patients.
Methods: The study included 47 patients (45 females, 2 males) aged 37,6 ±11,2 y with mean EN duration 2,5[1; 6] months who were on the record at V. A. Nasonova Research Institute of Rheumatology during 2013–2017 yy. All patients filled in EQ-5D, RAPID-3 and HADS questionnaires at baseline (first visit) and 12 months later. The sensitivity of the questionnaires was assessed by comparing obtained scores with patient's response to therapy until achievement of nodular regression at the time of dynamic examination. The construct validity was determined using a correlation analysis with "external criteria", such as presence of artralgia/arthritis, palpatory tenderness of nodules assessed with VAS scale, ESR and CRP levels.
Results: Complete nodular regression was achieved in 39 patients. Positive post-treatment changes (nodular regression) correlated with improved EQ-5D (EQ-5D-index – p=0,005, EQ-5D-VAS – *p*=0,009) and HADS-anxiety subscale – p=0,02. No significant association was found for other questionnaires with *p* value=0,11 for RAPID-3 and p=0,69 for HADS-depression scale. Moderate correlation was established at control visit after 12 months (Mo12) between EQ-5D-index and nodular tenderness to palpation (r=–0,49, p=0,0001), between EQ-5D-index and ESR value (r=–0,55, p=0,0016), as well as between general health status assessed by VAS and nodular tenderness to palpation at baseline visit (r=–0,56, p=0,0001), indicating close association of data obtained by these assessment tools with objective physical and laboratory findings. There was also moderate correlation between functional RAPID-3 scores and nodular tenderness to palpation at Mo12 (r=0,37, p=0,0172) and ESR level (r=0,52, p=0,0002). These data demonstrate close association of assessment scales performance with objective health status. Moderate correlation was established for HADS-depression subscale scores with nodular tenderness to palpation in 12 moth after initiation of treatment (r=0,41, *p*=0,0077) and CRP value (r=0,34, p=0,025). There were no additional statistically significant correlations for RAPID-3 and HADS subscales with clinical and laboratory findings.
Conclusions: EQ-5D questionnaire is a valid and sensitive tool for assessment of quality of life in EN patients.
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