report xerostomia with respect of those who reported xerostomia (31.8% vs 6.9%, $p = 0.02$). There were not associations between xerostomia and hypothyroidism, diabetes or menopause. The presence of Sjogren Syndrome was rule out in those 4 patients whose sialometry was positive.

Conclusions: The prevalence of xerostomia was 51%. No statistically significant associations were found in patients who reported xerostomia. A decrease in objective salivary flow was not demonstrated in patients with FM.

References:

- [1] The fibromyalgia impact questionnaire: development and validation" Burckhardt CS; " Validación de la versión española del Fibromyalgia Impact Questionnaire" S. Monterde.
- [2] " The American College of Rheumatology Preliminary Diagnostic Criteria for Fibromyalgia and Measurement of Symptom Severity".
- [3] " The American College of Rheumatology 1990 Criteria for the Classification of Fibromyalgia. Report of the Multicenter Criteria Committee.

Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2017-eular.2074

THU0480 MULTICENTER, PROSPECTIVE, CONTROLLED DOUBLE-BLIND STUDY COMPARING FIB-19-01, A PHYTOTHERAPY TREATMENT FOR FIBROMYALGIA, TO A DIETARY SUPPLEMENT AND TO CONVENTIONAL TREATMENT IN PATIENTS SUFFERING FROM FIBROMYALGIA

P. Bertin¹, D. Baron², M. Barmaki³, I. Russ⁴, C. Maindet-Dominici⁵, P. Fardellone⁶, P. Ginies⁷, T. Conrozier⁸, J. Nizard⁹. ¹Rheumatology, CHU Limoges, Limoges; ²Rheumatology, CH Lannion, Lannion; ³Pain, Clinique Mutualiste Eugène André, Lyon; ⁴Pain, Hôpital residence du Parc, Marseille; ⁵Pain, CHU Grenoble, Grenoble; ⁶Rheumatology, CHU Amiens, Amiens; ⁷Pain, CHU Montpellier, Montpellier; ⁸Rheumatology, Nord Franche Comté Hospital, Trevenans; ⁹Pain, CHU Nantes, Nantes, France

Background: Current therapeutic modalities for fibromyalgia syndrome (FMS) do not provide satisfactory results to a high percentage of patients and new approaches have to be explored.

Objectives: This randomised, double-blind, controlled study was aimed to assess the efficacy and safety of adding a new treatment of herbal medicine, specifically developed to improve the quality of life of patients with FMS (Fib-19-01), to the current therapeutic regimen.

Methods: In this double-blind, placebo-controlled study, females with FMS, insufficiently improved by their current treatments, were randomised in one of the 3 following arms: Patients of arm 1 received Fib-19-01, 1 tablet twice a day. Those of arm 2 received a food supplement claimed to have analgesic properties (FSAP), in a double-blind way, and patients of arm 3 continued the previous treatment without adding anything else (NoT). All continued the conventional treatment throughout the 6 months of follow-up. Inclusion criteria: women suffering from FMS (ACR criteria) with a Fibromyalgia Index Questionnaire FIQ >46. The primary endpoint was the change in FIQ score between baseline (Day 0) and month 6 (M6). Secondary Criteria included variation between D0 and M6 of the following scores: Pichot scale, Pittsburgh Sleep Quality Index (PSQI) index, SF-12 mental and social, SF-12 physical, HAD scales for depression and anxiety. Statistical analysis: Comparison intra-group (D0-M6) and intergroup on the ITT population.

Results: The ITT and per protocol populations were constituted of 101 and 75 patients. They were not statistically different and were in accordance with that expected (age 49, BMI 25, high percentage of antidepressant and anticonvulsant treatments). FIQ decrease throughout the follow-up was significant only in the Fib-19-01 group; ($p < 0.001$). In intergroup comparison, improvement was higher for Fib-19-01 (-13.5) than in the 2 other groups (-5.4 and -5.6) but the difference did not reach statistical significance ($p = 0.08$). Analysis of variance in repeated measurements of FIQ showed a significant difference between Fib-19-01 and FSAP ($p = 0.03$). On the secondary criteria, only Fib-19-01 patients were improved for PICHOT scale ($p < 0.001$), PQSI ($p = 0.02$), SF12 mental and social ($p < 0.001$), HAD anxiety ($p = 0.003$) and depression ($p = 0.004$). In intergroup comparison Fib-19-01 was superior to FSAP for Pichot scale ($p = 0.013$), mental and social SF12 ($p = 0.018$), HAD depression ($p = 0.013$). No significant difference was found between FSAP and NoT groups. Therefore, in this study FSAP acts as a placebo which gives the results of this study a level of evidence I. All treatments were well and similarly tolerated.

Conclusions: A 6-month treatment with Fib-19-01 improved all FMS scores excepted the physical SF 12, as opposed to FSAP and conventional treatment alone, which did not significantly improve any. This study showed that Fib-19-01 has a therapeutic effect in the FMS chiefly on the components "fatigue", "emotion and social life" and "depression" of the disease, without safety concern.

Disclosure of Interest: P. BERTIN: None declared, D. BARON: None declared, M. BARMAKI: None declared, I. RUSS: None declared, C. MAINDET-DOMINICI: None declared, P. FARDELLONE: None declared, P. GINIES: None declared, T. CONROZIER Consultant for: LABRHA SAS, J. NIZARD: None declared

DOI: 10.1136/annrheumdis-2017-eular.3790

THU0481 VALIDATION OF THE PROPOSED 2016 REVISION TO 2010 ACR PRELIMINARY FIBROMYALGIA DIAGNOSTIC CRITERIA IN A TERTIARY CARE SETTING

S. Ahmed, A. Aggarwal, A. Lawrence. *Clinical Immunology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow, India*

Background: The 2010 Fibromyalgia Diagnostic Criteria was designed for primary care¹. The 2011 modification was a simplified version for self-reporting of fibromyalgia². The 2016 revision combines both, and is supposed to be used also in tertiary setting³. This requires validation.

Objectives: To validate the Proposed 2016 revision with respect to (1) expert physician diagnosis and (2) 1990 ACR Classification Criteria.

Methods: Patients referred to a tertiary care centre with suspicion of Fibromyalgia were evaluated using the Proposed 2016 revision. Patients with other rheumatological diseases were excluded. Considering the expert physician opinion and American College of Rheumatology (ACR) 1990 Classification as gold standards, sensitivity, specificity, and likelihood ratios were calculated. Also, validated Hindi language versions of Brief Patient Health Questionnaire (BPHQ), Generalised Anxiety Disorder-7 (GAD7), and Toronto Alexithymia Scale-20 (TAS20) were filled up by the participants.

Results: Out of 101 patients, 77 were diagnosed as Fibromyalgia by the expert. The 2016 criteria and ACR1990 criteria were met by 79 and 67 patients respectively. The 2016 had high sensitivity but much lower specificity as compared with either the expert diagnosis or ACR1990 criteria (Table 1). Visual Analogue Scale (VAS) for pain, BPHQ, GAD7, and TAS20 scores were 7.2 ± 2.3 , 14.1 ± 5.1 , 11.3 ± 5.5 and 58.0 ± 14.0 (Mean $\pm$ SD) respectively. Patients with or without fibromyalgia as per each of the three criteria had no significant difference in these scores.

Table 1. Sensitivity, Specificity, Likelihood ratios as compared to other criteria as gold standard, and agreement with the same

	2016 modification vs Expert opinion	2016 modification vs ACR 1990 criteria	ACR 1990 criteria versus Expert opinion
Sensitivity	87%	89.5%	79.2%
Specificity	50%	44.1%	75%
Positive likelihood ratio	1.74	1.60	3.17
Negative likelihood ratio	0.26	0.24	0.28
Kappa	0.38	0.37	0.47

Conclusions: Non-tender point based criteria have been validated in primary care. However, in tertiary care where patients are referred to as fibromyalgia, there are mimics with similar comorbidities as evident by high BPHQ, GAD7 and TAS20 scores. Even after exclusion of other rheumatological conditions, the 2016 Criteria has poor specificity. Thus, it should be used as a screening tool than a diagnostic criterion in tertiary care.

References:

- [1] Wolfe F, Clauw DJ, Fitzcharles MA, Goldenberg DL, Katz RS, Mease P, Russell AS, Russell IJ, Winfield JB, Yunus MB. The American College of Rheumatology preliminary diagnostic criteria for fibromyalgia and measurement of symptom severity. *Arthritis Care Res (Hoboken)*. 2010 May;62(5):600-10.
- [2] Wolfe F, Clauw DJ, Fitzcharles MA, Goldenberg DL, Häuser W, Katz RS, Mease P, Russell AS, Russell IJ, Winfield JB. Fibromyalgia criteria and severity scales for clinical and epidemiological studies: a modification of the ACR Preliminary Diagnostic Criteria for Fibromyalgia. *J Rheumatol*. 2011 Jun;38(6):1113-22.
- [3] Wolfe F, Clauw DJ, Fitzcharles MA, Goldenberg DL, Häuser W, Katz RL, Mease PJ, Russell AS, Russell IJ, Walitt B. 2016 Revisions to the 2010/2011 fibromyalgia diagnostic criteria. *Semin Arthritis Rheum*. 2016 Dec;46(3):319-329.

Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2017-eular.2566

THU0482 EVOLUTION OF COMORBID FIBROMYALGIA FREQUENCY IN AXIAL SPONDYLOARTHRITIS PATIENTS STARTING AN ANTI-TNF AGENT, AND CORRELATION TO ANTI-TNF EFFICACY. THE PREDICT-SPA STUDY

S. Perrot, A. Moltó, A. Etcheto, N. Boudersa, P. Claudepierre, N. Roux, F. Berenbaum, A. Martin, L. Sparsa, P. Coquerelle, M. Soubrier, L. Gossec, M. Dougados. *Predict-SpA Study Group, Paris, France*

Background: Fibromyalgia (FM) is a frequent comorbid condition in axial spondyloarthritis (axSpA). It is not known how FM comorbidity may respond to the management of SpA, and especially to anti-TNF agents.

Objectives: To evaluate the change of comorbid FM status of axSpA patients starting an anti-TNF treatment.

Methods: A prospective multicenter national study involving 39 rheumatology centers in France, analyzing 519 patients with axSpA requiring anti-TNF therapy (ClinicalTrials.gov: NCT03039088). Patients were screened for FM with the FIRST questionnaire before and after 3 months of anti-TNF. Kappa coefficient was calculated to determine the agreement of the FIRST at M0 and M3. Response to anti-TNF (BASDAI50 response was compared according to positive screening for FM or not, at both time-points using chi2 tests.

Results: Of the 519 enrolled pts, 504 (with complete data on the FiRST questionnaire) were analyzed at M3. A positive screening for comorbid FM was found in 192 pts (38%) at M0 and in 127 (25%) pts at M3. Correlation between FiRST at M0 and M3 was weak with a Kappa coefficient correlation of 0.4 [0.3 - 0.5].

Four groups were identified: group [+/-] with comorbid FM at M0 and M3: N=93 (18%); group [-/-] with comorbid FM at M0 but not at M3: N=99 (20%); group [-/-] without comorbid FM at M0 and M3: N=278 (55%); group [-/+] without comorbid FM at M0 but at M3: N=34 (7%)

Changes in the status of comorbid FM (disappearance or appearance) was observed in 134 pts (26%). In the 193 pts with baseline comorbid FM, after 3 months of anti-TNF treatment, comorbid FM was no longer found in 99 (51%)%. Efficacy at M3 was significantly better, according to BASDAI 50, in patients without comorbid FM at M3 (Table).

	FM status according to the FiRST questionnaire at M0/M3 (N total=504)			
	+/+	+/-	-/-	-/+
Number of patients	93	99	278	34
Number of patients reaching BASDAI 50 at M3	26 (28%)	61 (61.6%)	162 (58.3%)	8 (25.5%)

Conclusions: There is a high frequency of comorbid FM screened by the FiRST in active axSpA, decreased by 51% after 3 months of anti-TNF treatments. Persistence of FM after 3 months of anti-TNF treatment is associated with lower anti-TNF response. Further studies are required to analyze the impact of screening FM before starting anti-TNF therapy in axSpA.

References:

[1] Perrot S, et al. Development and validation of the Fibromyalgia Rapid Screening Tool (FiRST). *Pain*. 2010;150:250-6.

Acknowledgements: This study was conducted thanks to an unrestricted grant from MSD.

Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2017-eular.4688

THU0483 CHARACTERISTICS OF PATIENTS WITH ACTIVE AXIAL SPONDYLOARTHRITIS AND COMORBID FIBROMYALGIA. DIFFERENCES ACCORDING TO FIBROMYALGIA SCREENING (FIRST QUESTIONNAIRE) AND FIBROMYALGIA CLASSIFICATION (ACR1990)

S. Perrot, A. Moltó, A. Etcheto, N. Boudersa, P. Claudepierre, N. Roux, F. Berenbaum, A. Martin, L. Sparsa, P. Coquerelle, M. Soubrier, L. Gossec, M. Dougados. *Predict-SpA Study Group, Paris, France*

Background: Fibromyalgia (FM) can be a comorbid condition in axial spondyloarthritis (axSpA). FM screening questionnaires and classification criteria fulfillment may demonstrate different prevalence and patients' characteristics may differ.

Objectives: To evaluate frequency of comorbid FM, and the differences between axSpA patients with/without comorbid FM according to screening (FiRST) and classification tools (ACR1990 FM criteria).

Methods: A multicenter national study involving 39 rheumatology centers in France included 519 patients with axSpA starting an anti-TNF treatment (PredictSpA study; ClinicalTrials.gov: NCT03039088). Patients (pts) were screened for FM with the FiRST questionnaire and classified as FM by ACR 1990 criteria. Demographic characteristics, comorbidities, axSpA characteristics, CRP and imaging were recorded in all patients. Kappa coefficient (and its 95% CI) was calculated to compare FiRST and ACR1990 criteria. Baseline characteristics associated with FM were evaluated by univariable and multivariable logistic regression (including the variables with a p value < 0.20 in the univariable analysis).

Results: In the 519 pts (females: 46%, age: 42±12 years, mean BASDAI 5.7±2.0, mean ASDAS-CRP 3.3±0.9), a comorbid FM was screened in 38% and diagnosed in 16% of pts. Agreement between FiRST and ACR1990 was poor, with a Kappa coefficient of 0.2 [0.2-0.3].

In the multivariable analysis, comorbid FM (by the FiRST questionnaire) in axSpA

Table 1

Number of patients	Fibromyalgia according to FiRST questionnaire		Odds-ratio [95% CI]
	yes (199)	no (320)	
Education level (> high school)	72 (37%)	163 (51%)	0.6 [0.4 - 0.9]
Sick leave (yes)	108 (54%)	134 (42%)	1.5 [1.0 - 2.2]
Heel pain (yes)	127 (64%)	151 (47%)	1.6 [1.1 - 2.5]
Etanercept at baseline (yes)	63 (32%)	137 (43%)	0.6 [0.4 - 0.9]

Table 2

Number of patients	Fibromyalgia according to ACR 1990 criteria		Odds-ratio [95% CI]
	yes (84)	no (435)	
HLA B27 (positive)	27 (32%)	272 (63%)	0.39 [0.22-0.68]
Heel pain (yes)	61 (73%)	217 (50%)	2.03 [1.16-3.56]

patients was independently associated with a lower education level, more sick leave, more heel pain, more frequent second line anti-TNF. Comorbid FM defined by the ACR1990 classification criteria was independently associated with heel pain and inversely associated with B27 haplotype. (Table)

Conclusions: FM is frequently associated with active axSpA, with poor correlation between screening (FiRST) and diagnosis (ACR1990) test. Several characteristics are associated with comorbid FM, depending on FM classification and screening tools.

References:

[1] Perrot S et al. Development and validation of the Fibromyalgia Rapid Screening Tool (FiRST). *Pain*. 2010;150:250-6.

Acknowledgements: This study was conducted thanks to an unrestricted grant from MSD.

Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2017-eular.4702

THURSDAY, 15 JUNE 2017

Basic science in paediatric rheumatology

THU0484 RO60 EXPRESSION DECREASES WITH AGE IN PERIPHERAL BLOOD MONONUCLEAR CELLS OF CHILDREN AND ADOLESCENTS AND CORRELATES WITH TLR7 STIMULATION IN PDCs OF PREPUBERTAL CHILDREN

A. Radziszewska, K. Webb, H. Peckham, Y. Ioannou. *Arthritis Research UK Centre for Adolescent Rheumatology at University College London, Great Ormond Street Hospital and UCLH, University College London, London, United Kingdom*

Background: Auto-antibodies to the RNA binding protein Ro60 are present in patients with autoimmune disorders such as systemic lupus erythematosus (SLE). In addition to its established role as an auto-antigen, Ro60 has been found to bind Alu RNA retroelements whereby it may target Alu retroelement RNA for degradation suggesting a novel putative function of this auto-antigen. If Ro60 modulates the amount of cellular RNA then one may hypothesise an association with toll-like receptor (TLR) 7 stimulation threshold.

Objectives: To measure the physiological levels of intracellular Ro60 protein in healthy children and adolescents and investigate a possible link between Ro60 protein expression and interferon- α (IFN- α) production after TLR7 stimulation.

Methods: Peripheral blood mononuclear cells (PBMCs) were isolated from blood from 48 healthy children and adolescents (age range 6.7-17.9 years old). Cell lysates from thawed PBMC samples were tested for Ro60 expression by Western blot. PBMCs were also stimulated for 20 hours with TLR7/8 agonist R848, at 1ug/ml in the presence of brefeldin A, and plasmacytoid dendritic cell (pDC) IFN- α expression was measured using flow cytometry. Statistical tests to measure correlation between IFN- α expression in (pDCs) and PBMC Ro60 expression were performed using SPSS.

Results: Ro60 expression in PBMCs correlated negatively with age (Spearman's rho = -0.317, p=0.032). When participants were divided into two groups based on their self-reported puberty status, Ro60 expression was higher in the pre-pubertal group (p=0.02). There was, however, no difference in Ro60 expression between males and females (p=0.44) or when sexes were stratified according to pubertal status. pDC IFN- α production after TLR 7 stimulation, did not correlate with ex vivo PBMC Ro60 expression overall (Spearman's rho =0.159, p=0.302) however a moderate positive correlation was observed in pre-pubertal samples only (Spearman's rho =0.554, p=0.021).

Conclusions: Ro60 expression decreases with age in healthy young people. These findings need to be confirmed in a larger cohort and further studies are necessary to investigate the link between Ro60 expression and TLR7 signalling across different age groups as well as in patients with SLE.

Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2017-eular.5073

THU0485 POLYMORPHISM OF SOME GENES INVOLVED IN IMMUNE AND INFLAMMATORY RESPONSES IN BELARUSIAN PATIENTS WITH JUVENILE IDIOPATHIC ARTHRITIS AND OTHER ARTICULAR PATHOLOGY

H.A. Yatskiu¹, N.V. Nikitchenko¹, N.V. Savina¹, T.D. Kuzhir¹, A.M. Tchitchko², A.V. Sukalo², R.I. Goncharova¹. ¹*Institute of Genetics and Cytology, National Academy of Sciences of Belarus;* ²*Belarusian State Medical University, Minsk, Belarus*

Background: Etiology and pathogenesis of juvenile idiopathic arthritis (JIA), which prevails among pediatric rheumatic diseases, are insufficiently clear. The study of molecular-genetic basis of JIA is of great interest for revealing genetic predisposition and early diagnosis.

Objectives: The present study aimed to analyze seven SNPs in five genes involved in immune and inflammatory responses: *TNFA* (rs1800629, rs361525), *PTPN22* (rs24766012), *MIF* (rs755622, rs5844572), *CTLA4* (rs5742909), *STAT4* (rs754865), as well as in two DNA repair genes *XPD* (rs1799793) and *XRCC1* (rs25487) in different conditions.