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 prevalente of xerostomía 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.

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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

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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.

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

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Background: The 2010 Fibromyalgia Diagnostic Criteria was designed for primary care[1]. The 2011 modification was a simplified version for self-reporting of fibromyalgia[2]. The 2016 revision combines both, and is supposed to be used also in tertiary setting[3]. 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, BHPQ, GAD7, and TAS20 scores were 7.2±2.3, 14.1±5.1, 11.3±5.5 and 58.0±14.0 (Mean±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.

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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

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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.