Objectives: Compare the sexual function of women with and without FM.
Methods: Sexually active women aged between 19 and 65 years with and without medical diagnosis of FM in a single center, matched for age and menopausal status, were evaluated. The exclusion criteria were pregnancy and use of medications with urinary side effects (urinary loss or retention). In a single interview the participants signed the Informed Consent Form and answered questions about personal and gynecological data. The protocol The Sexual Quotient – Female Version (QS-F) was applied to assess sexual performance. We used for statistical analysis t test for independent variables and Mann-Whitney Test for the others.
Results: In this study, 126 women were evaluated with age of 43.73±10.48 years. Most of the patients were married, representing 58.7%. A total of 50% participants had 1 or 2 children, 22.2% between 3 and 4 children and 27.8% had no children. Regarding the age of menarche and manopausal status, no differences were observed between groups (p=0.70 and p=0.08, respectively). The QS-F score revealed significantly lower scores for women with FM when compared to the healthy group ($p<0.001$). We observed the same results in the domains: Desire and Sexual Interest ($p<0.001$), Excitation Phase (p=0.019) and Satisfaction and Orgasm ($p<0.001$). Regarding the Pain and Comfort domain, no differences were observed between the groups (p=0.307). However, when they were questioned about dyspareunia in the physiotherapeutic evaluation, it was observed that 51.6% of FM patients reported pain in sexual act against only 26.6% of healthy women (p=0.005).
Conclusions: Women with FM performed poorly on QS-F general score and in most domains, except for pain and comfort. When they were questioned in the physiotherapeutic evaluation about dyspareunia, we observed that women with FM had more pain in sexual intercourse, which may occurred due to the way the question was asked. As consequence, women with FM report worse sexual performance, especially with regard to desire, arousal phase and orgasm rate.
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THU0477 DOES FIBROMYALGIA AFFECT PHYSICAL ACTIVITY OF THE PATIENTS?

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Background: Fibromyalgia syndrome (FMS) as a chronic pain condition can cause impaired physical activity level of the patients.
Objectives: The purpose this case-control study was to evaluate the physical activity levels of patients with FMS and to assess a possible relation between physical activity and disease characteristics.
Methods: Seventy patients with FMS and 50 age-gender matched controls were included in the study. The demographic features and duration of symptoms of the participants were recorded. The level of pain was evaluated using the visual analogue scale (VAS). The Fibromyalgia Impact Questionnaire (FIQ) scoring system was used for the evaluation of the impact of FMS. Also for assessing the physical activity in our participants, we used The International Physical Activity Questionnaire (IPAQ). Mann–Whitney U and Pearson correlation tests were used for group comparisons and was used for correlation analyses.
Results: The mean age of the patients and healthy controls were 41,90±8,53 years and 41,52±9,01 years, respectively. Symptom duration of the patients was 61,0±45,8 months. The patients with FMS presented significantly less transportation-related, recreational and total physical activity levels, besides reporting significantly less time spent walking and less time spent in vigorous activities than healthy controls ($p<0,05$). Also, in patients with FMS, there was a negative correlation between pain and the scores of self-reported moderate or vigorous physical activity ($r =- 0.41$, $p<0.01$). However, we couldn't find any correlation between FIQ and IPAQ scores.
Conclusions: Patients with FMS are physically less active than healthy individuals of similar profile. This reduced activity seems to be associated with pain, but not with the impact of the disorder. In the approach to the patient with FMS, considering the patient's physical activity behavior can contribute to the management of the disorder. In future studies assessing the effect of exercise in FMS, consideration of the patients' physical activity level may contribute to a complete evaluation of the patients.
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THU0478 DETERMINATION OF COMORBIDITIES IN FIBROMYALGIA SYNDROME

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Background: Although fibromyalgia syndrome is diagnosed by excluding other possible diagnosis based on the patient's clinical features, in recent the studies, it was shown that comorbid diseases affect the course of fibromyalgia.
Objectives: The aim of this study is to evaluate the comorbid diseases of patients with fibromyalgia and to determine the rates of comorbid diseases
Methods: In this study, age, gender and comorbid diseases of patients above 18 years and diagnosed with fibromyalgia by a were evaluated in the database system of the hospital retrospectively.
Results: A total of 509 patients were examined in our study. 51 of the patients were male, 458 were female (mean age was 50.24±12.32). Of the patients, 345 (67.8%) had at least one comorbid disease while 164 (32.2%) had no comorbid disease. In the study, 187 of the patients (36.7%) had cardiovascular diseases, 157 of the patients (30.8%) had endocrine diseases, 63 of the patients (12.4%) had rheumatologic diseases, 30 of the patients (5.9%) had neurological diseases, 14 of the patients (2.8%) had other autoimmune diseases, 10 of the patients (2.0%) had cancers, 129 of the patients (25.3%) had mental disorders, 45 of the patients (8.8%) had chronic lung diseases, 37 of the patients (7.3%) had osteoporosis, 11 of the patients (2.2%) had other diseases (chronic pancreatitis, chronic renal failure, nephrotic syndrome, deep vein thrombosis, hepatitis serology positivity, pulmonary thromboembolism, organ transplantation).
Conclusions: FMS is an important disease that is increasing in frequency in recent years. FMS, which can be seen with many diseases, is in fact related to physicians from many branches, and it is useful to evaluate FMS patients with their comorbid conditions on their follow-up.
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THU0479 THE PREVALENCE OF XEROSTOMIA IN PATIENS WITH FIBROMYALGIA

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Background: Fibromyalgia (FM) is a rheumatic disease characterized by diffuse, chronic musculoskeletal pain, of non-articular origin, which is evidenced by the palpation of painful points in specific anatomical areas and is usually accompanied by non-repairing sleep, Tiredness, morning stiffness, cognitive alterations, among others.
FM affects approximately 0.5 -5% of the population, having a maximum prevalence between 40 and 50 years. No racial or socioeconomic predisposition has been determined to date.
Sicca syndrome whose term encompasses xerophthalmia, xerostomia, xeroderma and xerovagina, has been described in patients with FM. Xerostomia is the sensation of dry mouth due to lack or decrease of saliva. There are no clinical studies that determine the prevalence of xerostomia in patients with FM and on the other hand the reduction of salivary flow in these patients has not been studied with objective tests.
Objectives: The aim of this study was to determinate the frecuency of xerostomia in patients with diagnosis of Fibromyalgia and describe their clinical and epidemiologic characteristics.
Methods: Patients were included according 1990 and 2010 ACR Classification criteria. Patients taking drugs that cause xerostomia were excluded as well as the ones presenting other rheumatologic diseases. Xerostomia was assessed by interrogation and physical examination, and a sialometry was performed in order to determinate the decrease of salival flow. A sialometry was positive if the saliva flow was under 1.5 ml in 15 minutes. In case of presenting positive sialometry patients were studied to rule out Sjogren Syndrome with laboratory and minor salivary gland biopsy.
Results: 50 patients were recruited during the study. The 100% of them were women. The mean age was 47 years old (DS+-8.5), while the mean time of evolution of FM was 6 years. 29 patients reported xerostomia of which 4 presented positive sialometry. No positive sialometry was found in the group that did not referred xerostomia. Smoking was more prevalent in patients with FM who did not

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.