Results Patients with FM reported a mean pain score of 7.0 (+1.3) and mean sleep quality score of 6.5(+1.7) on the 0–10 point scale. Over 95% of patients selected the descriptors aching, tender and tiring-exhausting. The mean pain score as measured by the VAS of the SF-MPQ was 74.8(+14.2) on the 0–100 point scale. The mean number of tender points was 17.1(+1.5) of 18 possible; the mean Tender Point Pain Intensity Score (0–10 point scale) was 6.1(+1.8), while control point mean pain severity was 2.0(+1.9).

Conclusion Patients with FM reported a moderate to severe level of pain and sleep disturbance. Pain severity was consistently reported across the three measures of pain, the daily pain diary, the VAS, and the Tender Point Pain Intensity Score. Nearly all patients consistently described their pain as tender, aching and tiring-exhausting. Additional studies need to be completed to characterise further the pain and sleep disturbance prevalent in patients with FM, and to assess and define other symptoms involved in the FM syndrome (see companion abstract by Sesti, *et al.*).

SAT0139 A CONTROLLED LONG-TERM TREATMENT OF FIBROMYALGIA PATIENTS WITH SERTRALINE

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Background The pathophysiology of Fibromyalgia syndrome (FM) is mostly uncertain and the conventional medication therapy results from empirical research. FM is a common disorder that is estimated to affect 2–4% of the population. Serotonin reuptake inhibitors are now used in FM due to their interference in the serotonin metabolism.

Objectives To evaluate the relative efficacy and tolerability of Sertraline in the long-term treatment of fibromyalgia patients.

Methods Fifty patients who fulfilled the American College of Rheumatology criteria for the classification of fibromyalgia were entered in a 6-month prospective, controlled trial; all patients were treated with Sertraline (50–100 mg/day). Symptomatic treatment with nonsteroidal anti-inflammatory drugs (NSAIDs) and/or analgesic was allowed at optimal doses that were established on the basis of each patient's needs. Five control examinations were planned (at baseline, after 15 days at month 1, 2, 3, and 6). Primary efficacy measures were (1) patient self assessment of pain on a 10 cm visual analogue scale (VAS), (2) tender point index (TPI) which is the sum of individual tenderness severity at each of the 18 standard ACR tender points and (3) Fibromyalgia Impact Questionnaire (FIQ). Other six secondary clinical efficacy measures were selected: physician and patients' global assessment of the disease, sleep quality assessment using a 100-mm visual analogue scale, Health Assessment Questionnaire (HAQ) the Hamilton rating scale for depression (HRSD) and the Hamilton rating scale for anxiety (HRSA). Tolerability assessment was based on the occurrence of any adverse events.

Results All primary efficacy measures were significantly improved after 1 month of treatment ($p < 0.05$) and maintained a significant improvement throughout the study. No further improvement was however observed after 3 months of treatment. Most of the secondary efficacy measures improved significantly; in particular HRSD and HRSA ($p < 0.01$) improved after 1 month of treatment. After 6 months of treatment, 23 patients (45%) were still on treatment with Sertraline. Most of

the withdrawals were due either to inefficacy (12 patients), side-effects (7 patients) or lost to follow-up (8 patients).

Conclusion Our data confirm the long-term efficacy of sertraline in a discrete percentage of patients with fibromyalgia.

SAT0140 HYPERSOMNOLENCE IN FIBROMYALGIA SYNDROME

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Background

Objectives To evaluate hypersomnolence in patients affected by fibromyalgia syndrome.

Methods Thirty consecutive patients affected by fibromyalgia syndrome (FMS) (28 F) underwent a general sleep questionnaire, the Epworth sleepiness scale (ESS), formal polysomnography, and lung function tests.

Results Patients complaining of daytime hypersomnolence had a higher number of tender points (15 ± 2 vs 12 ± 1 , $p < 0.01$), a greater score of subjective pain (72 ± 15 vs 52 ± 13 , $p = 0.05$) and more fatigue ($p = 0.04$), about twice as many arousals per hour and a lower sleep efficiency than patients who did not report this symptom. TLco was more impaired and the occurrence of PB higher.

FMS patients who referred daytime somnolence slept significantly less efficiently than the FMS with no day time somnolence ($p < 0.05$), had a lower proportion of stage 3 sleep ($5 \pm 2\%$ vs $12 \pm 3\%$; $p < 0.001$), stage 4 ($1 \pm 0.5\%$ vs $4 \pm 1\%$; $p < 0.001$), and twice as many arousals per hour of sleep ($p < 0.01$). The respiratory pattern of FMS patients with hypersomnolence showed a higher occurrence of periodic breathing ($p = 0.02$). The short length of apneas and hypopneas did not affect the apnea/hypopnea index (5.1 ± 3 vs 7 ± 4 ; $p = \text{ns}$), but FMS patients with daytime hypersomnolence had a greater number of desaturations per hour of sleep (11 ± 6 vs 6 ± 5 ; $p < 0.05$). Pulmonary volumes did not differ between the two groups.

Conclusion The occurrence of daytime hypersomnolence in FMS patients, is linked to a greater severity of fibromyalgia symptoms and to a more severe polysomnographic alterations.

SAT0141 THE EFFECTS OF MIRTAZAPINE IN THE TREATMENT OF FIBROMYALGIA SYNDROME

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Background Some previous study has documented the efficacy of 5-HT₃ receptors antagonists in the treatment of fibromyalgia.

Objectives The mirtazapine (Remeron), a new generation antidepressive agent, characterised by blocking of 5-HT₂ and 5-HT₃ receptors and stimulation of 5HT-1 and noradrenergic receptors was used in the treatment of patients with Fibromyalgia syndrome (FS).

Methods Twenty patients (18 female, 2 male), age range 20–64 years, mean 43.58, fulfilling the 1990 ACR criteria for fibromyalgia, entered 6 weeks open study and were given 30 mg mirtazapine per day. Before the administration of the first dose, during the study and at the final visit, the following parameters were measured using the visual analogue scale 0–10 (VAS): pain,

morning stiffness (minutes) fatigue, sleep disturbances and other vegetative and functional symptoms. Severity of depression was also evaluated with Hamilton Depression Rating Scale, 17-item version (HDRS).

Results 12 from 17 patients (70%) showed a clinical improvement at the end of the study as a consequence of the reduced intensity of pain (8,1 before, 4,6 after therapy, $p < 0,001$), morning stiffness (57,6 min. vs 36,8 min., $p < 0,005$), fatigue (8,3 vs 5,3, $p < 0,001$), sleep disturbances (8,2 vs 2,5, $p < 0,0005$), headache (7,1 vs 4,2, $p < 0,005$), gastrointestinal symptoms (6,1 vs 2,4, $p < 0,005$) or paresthesia (8,5 vs 4,8, $p < 0,005$). The reduced severity of depressive symptoms was also observed (17,7 vs 6,8, $p < 0,001$). Six patients complained of sleepiness and hypotension during the first days of therapy, in three cases dose of mirtazapine was reduced to 15 mg and treatment continued, three patients (female) were excluded from the study.

Conclusion Our data suggest that mirtazapine could be an effective and promising method in the treatment of fibromyalgia patients. During the treatment of FS patients strict cooperation between rheumatologists and psychiatrist is needed.

SAT0142 EFFICACY ANALYSIS OF LOW-ENERGY LASER THERAPY IN TREATMENT OF FIBROMYALGIA

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Background

Objectives The aim of the study was to investigate the efficacy of low-energy laser therapy versus placebo in treatment of patients with fibromyalgia.

Methods We followed 36 female patients (age from 31 to 51 years, mean age 41.94 years) with fibromyalgia according to latest American College of Rheumatology (ACR) criteria for diagnosis. The first group of 18 patients was treated with low-energy laser 10 times every other day by scanning each of tender points with single therapy dose of 40 J. Identical procedure was performed in the second group of 18 patients, but low-energy laser diode was switched-off. All patients from both groups took similar drugs – NSAIDs and benzodiazepines, also had similar low-impact and stretching exercises. We measured the count of tender points, pain intensity with four-scale questionnaire; also sleep disturbance and malaise with similar four-scale questionnaire, before and after therapy procedure. Results were statistically analysed with Wilcoxon matched pairs test within groups of patients and with Mann-Whitney U test between groups.

Results In both groups we found statistically significant lowering of count of tender points ($p < 0.001$), pain intensity ($p < 0.001$), sleep disturbance ($p < 0.001$) and malaise ($p < 0.001$ in the first group and $p < 0.05$ in the second) after therapy procedure. Between groups we found that lowering of all followed disease parameters was more clearly in the first group and all differences were statistically significant ($p < 0.0001$ for all parameters).

Conclusion Treatment of patients with fibromyalgia with low-energy laser therapy improves symptoms of disease more than placebo. This statement suggests that low-energy laser therapy have prominent place in up to date treatment of patients with fibromyalgia, especially because of patient's tolerance, no contraindications and simple applicability.

SAT0143 PSYCHOSOMATIC ASPECTS OF FIBROMYALGIA VERSUS RHEUMATOID ARTHRITIS

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Background The psico-social dimensions of fibromyalgia (FM) remain controversial, not only regarding its characterisation but also its possible causal or consequential relationship with the chronic pain status. The usual discrepancy between the self-report instruments of functional impairment and the observed disability favours a process of somatization. The contribution of pain and emotions to general health status are open to debate.

Objectives We attempted to investigate emotional disturbances in patients with fibromyalgia and rheumatoid arthritis (RA) and their relationship with self-reported general health.

Methods 58 FM patients and 43 RA patients, fulfilling the ACR criteria, were included on a consecutive basis from our Rheumatology outpatient clinic. Social and demographic data were collected and found to be comparable among the groups, as well as disease duration. The Short-Form Health Survey (SF-36) and the Brief Symptom Inventory (BSI) were applied twice, with 6 months interval. Both instruments were evaluated regarding each of their different dimensions and summary score. Statistical analysis employed Student's t test.

Results FM patients scored significantly higher in every single BSI dimension (somatization; obsession/compulsion; interpersonal relationship; depression; anxiety; hostility; phobic anxiety; paranoid ideation and psychoticism). FM patients also showed significantly lower levels of general health, as evaluated by SF-36, both in mental and physical components. These differences remained stable in re-evaluation.

Conclusion FM patients have a higher score for associated psychopathologic symptoms. This parallels their higher dissatisfaction with general health, not only in its mental aspects, but also on physical function and performance. These results demonstrate a strong coexistence of pain and psychopathological traits in FM patients, which may have a strong influence on reported functional status. The possibility that such psychological disturbances are a consequence of the disease, and especially chronic pain, is questioned by the much lower prevalence of such disorders in RA patients of similar disease duration.

SAT0144 THE 24-HR URINARY EXCRETION OF 6-SULPHATOXYMELATONIN AND 5-HYDROXYINDOLEACETIC ACID IN WOMEN WITH PRIMARY FIBROMYALGIA AND CHRONIC LOW BACK PAIN

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Background Fibromyalgia syndrome (FS) is characterised by chronic "widespread" musculoskeletal pain, presence of multiple tender points, fatigue, depression/anxiety, and sleep disturbance. Recently, evidence has accumulated to link the FS pathogenesis to serotonin (5-hydroxytryptamine, 5-HT) deficiency. Since melatonin, a pineal hormone responsible for the regulation of sleep