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'Evidence based medicine in CL psychiatry and psychosomatics'**

A selection of the best abstracts submitted
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1 - Antidepressant treatment in patients with fibromyalgia and comorbid major depressive disorder.

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Background and aims: Fibromyalgia is a chronic, often debilitating musculoskeletal pain disorder that is characterized by widespread pain and muscle tenderness, and often accompanied by fatigue, stiffness, morning generalized rigidity, paresthesias, sleep agitation, with consequent disability and low quality of life (Patkar, 2003). About 30% of patients with fibromyalgia have mental disorders, mainly of the anxious-depressive type. The objectives of this study were to assess the use of duloxetine (SNRI) and bupropion (NDRI) in patients with fibromyalgia in comorbidity with current major depressive disorder and to highlight an eventual correlation between therapeutic response and quality of life, pain and depression.

Methods: The study involves a sample of 80 women aged 30-65 years with diagnosis of fibromyalgia in comorbidity with DDM. Patients will be subjected to a battery of tests including HAM-D, STAI I/II, BPI, FIQ, QL-INDEX, McGill Pain Questionnaire and TCI at beginning and every four month until the end of the research (12° months). Afterwards, the patients, will be subdivided in two parallels groups: Group A will take duloxetine (60mg) and Group B will take bupropion (150mg). The allocation to each group will be made in a sequential modality.

Results: Duloxetine has been shown to be an effective and safe treatment for many of the symptoms associated with fibromyalgia.

Conclusions: Antidepressants play an important role in the treatment of fibromyalgia symptoms and health-related quality of life.

2 - Conversion disorders in neurology; positive signs and diagnosis

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Background: In the sixties, conversion disorders (CD) were ill defined and frequently led to diagnosis failures. Long-term follow-up examinations were claimed to reveal an organic origin to CD symptoms in up to 30% of patients. Since the nineties, functional brain imaging (SPECT, fMRI) and neurobiological models revived the interest in CD. Clinical definitions and description of positive diagnostic signs have been refined and, for some, validated.

Aims: This session will review the diagnosis criteria of CD and focus on the neurological aspects of CD symptoms presentation. Recently validated signs (Hoover's sign, ictal eye closure, the "chair sign", the "Teddy bear sign") and current available criteria such as the recently published psychogenic movement disorders' criteria will be presented.

Results and conclusions: CD is no more understood as a "default" diagnosis supported only by the absence of evident organic cause. CD diagnosis requires a careful history and a complete clinical examination, looking for positive CD signs and, when available, validated signs. This approach will limit the risk of misdiagnosis.

3 - Psychiatric impairment in migrant patients attending the centre of mental health of Codroipo, Friuli region, Italy

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Alcoholism has a pronounced effect on people's mental and physical health. Glutamate dehydrogenase (GLDH) is a linking factor in metabolism of carbohydrates and proteins. It is an enzyme of mitochondrial matrix, but it is also found in rough endoplasmic reticulum. There is few relevant data about the role of GLDH in leukocytes and the effect of alcohol on leukocytes so far.

The aim of our study was to define GLDH activity in leukocytes under and after alcohol consumption, what can give us indirect data about protein metabolism in leukocytes.

We developed our own method to define GLDH activity and established our own reference activities for GLDH in leukocytes which were from 0.05 - 1.17 μ kat/g protein.

Our research has been done on 142 healthy subjects and 113 alcoholics having consumed alcohol within last 48 hours.

Mean catalytic activity in healthy subjects was 0.5649 μ kat/g protein. Mean catalytic GLDH activity in alcoholics increased from 0.5042 μ kat/g to 0.6696 μ kat/g after 24 - 48 hours to 0.6974 μ kat/g after 48 - 72 hours of abstinence. We found a statistically significant increase ($p = 0.012$) in GLDH activity after 48-72 hours of abstinence.

It is possible to conclude that under the influence of alcohol the leukocyte GLDH activity in alcoholics is lower than in healthy subjects. Cessation of alcohol consumption has resulted in a statistically significant increase in leukocytes GDLH activity. Therefore, alcohol consumption results in reduction in GLDH activity as well as protein production and consecutively leads to diminished leukocytes protective ability.

P0079

Pregabalin improves pain in fibromyalgia (FM) patients regardless of baseline anxiety and depression levels

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Aims: Examine the evidence for a relationship between pregabalin effect on pain and baseline anxiety and depressive symptoms in patients with fibromyalgia (FM).

Background: Chronic pain and concomitant anxiety and depressive symptoms are common in patients with FM, as well as in other chronic pain disorders. Pregabalin was effective for treating pain in FM patients in three parallel group RCTs (105, 1056, 1077) where data for anxiety and depressive symptom levels were collected.

Design/Methods: Patients meeting ACR criteria for FM with a pain VAS score ≥ 40 mm were followed for 8-14 weeks in 3 randomized, double-blind, placebo-controlled trials. Patients (N=2022) received 150, 300, 450 or 600mg/d pregabalin or placebo. The primary efficacy parameter was change in endpoint Mean Pain Score (MPS) (range 0 [no pain]-10[worst possible pain]). Regression analyses evaluated whether changes in pain bore any relation to the baseline Hospital Anxiety and Depression Scales (HADS-A) and (HADS-D) levels.

Results: Pregabalin 300, 450, and 600 mg/d, but not 150 mg/d, showed statistically significant improvements in pain compared with placebo ($p < 0.0001$). For each pregabalin treatment group, improvements in pain at endpoint were not found to have a statistically significant association with baseline levels of anxiety or depressive symptoms. Adverse events (AEs) were consistent with known side effects of pregabalin: dizziness and somnolence, mild to moderate in

intensity, were the most frequently reported AEs for pregabalin patients.

Conclusions/Relevance: Pregabalin treatment demonstrated significant improvements in pain regardless of baseline anxiety or depressive symptom levels for patients with FM.

Study funded by Pfizer, Inc

P0080

Efficacy of Pregabalin and Venlafaxine-XR in generalized anxiety disorder: Results of a double-blind, placebo-controlled 8-week trial

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Background and Aims: To compare the anxiolytic efficacy and speed of onset of pregabalin (PGB) and venlafaxine-XR (VXR) in patients with GAD.

Methods: Adult outpatients with DSM-IV GAD and a HAM-A score > 20 were randomized to 8-weeks of flexible-dose double-blind treatment with PGB 300-600mg/d (n=121), VXR 75-225mg/d (n=125), or placebo (PBO; n=128). Primary outcome: LOCF-endpoint change in HAM-A total score. Secondary outcomes included the Clinical Global Impression, Severity scale (CGI-S).

Results: Study groups were similar at baseline, or PGB, VXR, and PBO, respectively, in terms of gender, mean age, and baseline HAM-A (27.6 \pm 0.4 vs. 27.4 \pm 0.4 vs. 26.8 \pm 0.4). Treatment with PGB was associated with significantly greater improvement than placebo at LOCF-endpoint, with onset of treatment effect beginning by day 4. HAM-A-total scores for PBO, PGB, and VXR at day 4 were: -3.4 \pm 0.5, -5.3 \pm 0.5 (P=.008), and -2.9 \pm 0.6 (P=.070), respectively; corresponding LOCF-endpoint HAM-A-total scores were: -11.7 \pm 0.9, -14.5 \pm 0.9 (P=.03), and -12.0 \pm 0.9 (P=.097). LOCF-endpoint CGI-S scores for PBO, PGB, and VXR were: -1.5 \pm 0.2, -2.0 \pm 0.2 (P=.02), and -1.7 \pm 0.2 (P=.36).

Severe AE rates were: PGB (9.1%), VXR (20.0%), and PBO (7.8%). Discontinuation due to AEs were: PGB (12.4%), VXR (17.6%), and PBO (5.5%).

Conclusions: Pregabalin was safe and effective, demonstrating significantly earlier onset of anxiolytic activity against GAD than venlafaxine-XR. Venlafaxine-XR did not demonstrate significant efficacy, possibly due to a relatively high placebo response.

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P0081

Rapid onset anxiolytic efficacy after a single dose of Pregabalin: Double-blind, placebo-controlled evaluation using a dental anxiety model

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Background and Aims: To assess the speed of onset of anxiolytic efficacy of a single-dose of pregabalin (PGB) in a dental-anxiety model.

Methods: Adult outpatients in this double-blind, parallel-group study received a single-dose PGB 150mg (n=27), alprazolam 0.5mg (n=31; ALP), or placebo (n=31; PBO) 4 hours before a dental procedure. Inclusion criteria included Dental Anxiety Total score ≥ 12 (moderate-to-severe) without presence of DSM-IV anxiety disorder. Efficacy and safety assessments (at 2, 2.5, 3, 3.5, and 4 hours