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 μkat/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 μkat/g protein. Mean catalytic GLDH activity in alcoholics increased from 0.5042 μkat/g to 0.6696 μkat/g after 24 - 48 hours to 0.6974 μkat/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

T. Leon [1], E. Whalen [1], L. Arnold [2], L. Pauer [3], J. Barrett [1]. [1] *Pfizer Global Pharmaceuticals, New York, NY, USA* [2] *University of Cincinnati, Department of Psychiatry, Cincinnati, OH, USA* [3] *Pfizer Global R&D, Ann Arbor, MI, USA*

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

T.K. Murphy [1], G. Nivoli [2], A. Petralia [3], F. Mandel [1]. [1] *Pfizer Global Pharmaceuticals, Pfizer Inc, New York, NY, USA* [2] *Universita' Di Sassari, Sassari, Italy* [3] *Clinica Psichiatrica, Universita' Di Catania, Catania, Italy*

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-bind 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±0.4 vs. 27.4±0.4 vs. 26.8±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±0.5, -5.3±0.5 (P=.008), and -2.9±0.6 (P=.070), respectively; corresponding LOCF-endpoint HAM-A-total scores were: -11.7±0.9, -14.5±0.9 (P=.03), and -12.0±0.9 (P=.097). LOCF-endpoint CGI-S scores for PBO, PGB, and VXR were: -1.5±0.2, -2.0±0.2 (P=.02), and -1.7±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.

Funded by Pfizer Inc

P0081

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

T.K. Murphy [1], D. Nutt [2], F. Mandel [1]. [1] *Pfizer Inc., New York, NY, USA* [2] *University of Bristol, Bristol, UK*

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

https://doi.org/10.1016/j.eurpsy.2008.01.370 Published online by Cambridge University Press