P02.32

Amisulpride vs olanzapine in schizophrenia. Preliminary results on short-term analysis

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This trial was set up to compare the efficacy and safety of amisulpride (AMI) versus olanzapine (OLZ).

Patients with schizophrenia/schizophreniform disorder were randomized to AMI or OLZ. Treatment duration is 6 months. Analysis includes the first 203 randomized patients (ITT 199 patients, 97 for AMI ; 102 for OLZ) and is performed on the first 2 months of treatment.

143 patients completed the 2-month trial (69% of AMI, 72% of OLZ). The improvement observed on the BPRS score was of 14.3 points for AMI and 13.1 for OLZ; this results confirmed the hypothesis of non-inferiority of AMI ($p<0.001$). Improvement measured with BPRS subscores, PANSS total, positive and negative scores and CGI was also similar in both groups. Significantly more AMI patients ($p=0.03$) with substantial symptoms of depression ($MADRS\geq16$) at baseline remitted ($MADRS\leq10$) at endpoint. Changes observed on extrapyramidal symptoms were low and not different between the 2 groups. Weight gain observed during the study was significantly greater ($p<0.0001$) with OLZ (+2.7kg) than with AMI (+0.4kg).

These preliminary results indicate similar efficacy of the 2 in acutely ill schizophrenic patients. However, the safety profile was in favor of AMI with respect to weight gain.

P03. Anxiolytics

P03.01

Patient and observer perspectives on venlafaxine ER efficacy in GAD

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Treatment efficacy of psychotropic treatments may be assessed either by an external observer/physician or by the patients themselves. Perceptual alterations have been reported for patients with anxiety, suggesting that self- and observer-rated evaluation of anxiety severity may differ in sensitivity. Changes in anxiety severity scores and response rates for observer-rated (Hamilton Anxiety Rating Scale; HAM-A) and patient-rated (Hospital Anxiety and Depression Scale – anxiety subscale; HADS-a) assessment during treatment with venlafaxine ER in patients with generalised anxiety disorder (GAD) were compared.

Data from 2, 6-month duration, placebo-controlled trials of venlafaxine ER were pooled (N = 792). For both HAM-A and HADS-a, response was defined as 50% decrease in score from baseline. Remission on HAM-A and HADS-a were defined by an absolute score =<7 and =<3 respectively.

Compared with placebo, venlafaxine ER significantly improved HAM-A and HADS-a scores, response and remission rates. The HAM-A and HADS-a showed similar patterns of changes over time, both for total mean scores and for response rates. The results show that self-assessment of change in anxiety severity is at least as sensitive as observer-assessment.

P03.02

Do baseline gastrointestinal symptoms alter venlafaxine ER efficacy?

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Anxiety is often associated with somatic symptoms, particularly gastrointestinal (GI) symptoms. Serotonin reuptake inhibitors are associated with the occurrence of GI symptoms such as nausea. The impact of baseline severity of GI symptoms upon the efficacy and safety of venlafaxine extended release (ER), a serotonin and noradrenaline reuptake inhibitor, was investigated in patients with general anxiety disorder (GAD).

Data were pooled from 5 placebo-controlled, double-blind, randomised studies with venlafaxine ER. GI symptom severity was defined according to item 11 of the HAM-A scale: scores <=2 defined patients with no-to-moderate GI symptoms (82.4%), whereas scores >2 defined patients with severe GI symptoms (17.6%).

Venlafaxine ER was more effective than placebo in reducing HAM-A anxiety severity score, including psychic and somatic factors of anxiety, regardless of GI symptom severity. In the moderate GI subgroup, the emergence of nausea or the rates of discontinuation of patients for any adverse event were higher with venlafaxine ER than with placebo. However, these rates were not different for venlafaxine ER and placebo in the severe GI subgroup, indicating no additional risk.

P03.03

Duration of treatment with venlafaxine ER in GAD

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Generalized anxiety disorder (GAD) is a chronic disorder. It is not known how long treatment should continue once a response is obtained, nor how long treatment should persist in the absence of response. In this analysis, data from two placebo-controlled 6-month trials of venlafaxine ER (37.5 –225 mg/day) in GAD patients (ITT population: 767) were pooled. Criteria of response (>=50% improvement in HAM-A score) and remission (HAM-A score =<7) were used. The analysis aims to compare at each visit the percentage of nonresponders (or nonremitters) who become responders (or remitters) at month 6.

The percentage of nonresponders who became responders at month 6 was statistically significantly greater with venlafaxine ER than with placebo up until week 8 of treatment, but not beyond. The percentage of nonremitters who became remitters at month 6 was statistically significantly greater with venlafaxine ER than with placebo at all time points.

Conclusions: Treatment of patients with GAD should persist for at least 8 weeks even in the absence of response, while treatment to obtain remission should continue beyond this time point.

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