

**Background:** Previous studies on the prevalence of metabolic syndrome in patients with bipolar disorder have reported higher rates than in their respective general populations.

**Objective:** This study evaluates the prevalence rate and modal subcomponents of metabolic syndrome in 34 patients treated in University Hospital Centre Zagreb, Croatia.

**Method:** Naturalistic, cross sectional study. Patients were evaluated for the presence of metabolic syndrome according to NCEP ATP-III criteria.

**Results:** Mean age was 41.1 (SD 12.9). Overall prevalence rate of MetS was 35.3%. Forty seven percent met the criterion for abdominal obesity, 58.8% for hypertriglyceridemia, 23.5 % for low HDL cholesterol, 50.0% for hypertension, and 23.5 for high fasting glucose. There was no difference in the prevalence rate by gender.

**Conclusions:** Clinical medical monitoring for these parameters is recommended. Psychotropic drugs use may confer differential risk for developing the metabolic syndrome.

## P0160

A double-blind, placebo-controlled study with acute and continuation phase of Quetiapine and Lithium in adults with bipolar depression (Embolden I)

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**Background and Aims:** Evaluate the efficacy and tolerability of quetiapine and lithium monotherapy for major depressive episodes in bipolar disorder during an acute 8-week period and up to 52-week continuation phase.

**Methods:** 802 patients (499 bipolar I, 303 bipolar II) were randomized to quetiapine 300mg/d (n=265), quetiapine 600mg/d (n=268), lithium 600mg/d (n=136), or placebo (n=133) for 8 weeks. Primary endpoint was change from baseline to 8 weeks in MADRS total score. After 8 weeks, patients with MADRS  $\leq 12$  and YMRS  $\leq 12$  entered a 26- to 52-week continuation phase of quetiapine (300mg/d or 600mg/d) or placebo. Patients on lithium received 300mg/day of quetiapine (results of continuation phase not included here and to be presented separately).

**Results:** LSM MADRS score change at 8 weeks was -15.36 (quetiapine 300mg/d), -16.10 (quetiapine 600mg/d), -13.60 (lithium), and -11.81 (placebo;  $P < 0.001$  for both quetiapine doses,  $P = 0.123$  for lithium, versus placebo; LOCF ANCOVA). Quetiapine (both doses)-treated, but not lithium-treated, patients showed significantly greater improvements ( $P \leq 0.05$ ) in MADRS response and remission rates, HAM-D, CGI-BP-S, CGI-BP-Change, and HAM-A at Week 8 versus placebo; MADRS item 10 (suicidal thoughts) improved with quetiapine 600mg/d versus placebo ( $P = 0.013$ ). Most common adverse events considered drug-related included somnolence, dry mouth, and dizziness with quetiapine (both doses) and nausea with lithium.

**Conclusions:** Quetiapine (300mg/d or 600mg/d) was more effective than placebo for the treatment of acute depressive episodes in bipolar I and bipolar II disorder. Quetiapine treatment was generally well tolerated.

Supported by funding from AstraZeneca Pharmaceuticals LP.

## P0161

A double-blind, placebo-controlled study with acute and continuation phase of Quetiapine and Paroxetine in adults with bipolar depression (Embolden II)

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**Background and Aims:** Evaluate efficacy and tolerability of quetiapine and paroxetine monotherapy for major depressive episodes in bipolar disorder during an acute 8-week period and up to 52-week continuation phase.

**Methods:** 740 patients (478 bipolar I, 262 bipolar II) were randomized to quetiapine 300mg/d (n=245), quetiapine 600mg/d (n=247), paroxetine 20mg/d (n=122), or placebo (n=126) for 8 weeks. Primary endpoint was change from baseline to 8 weeks in MADRS total score. After 8 weeks, patients with MADRS  $\leq 12$  and YMRS  $\leq 12$  entered a 26- to 52-week continuation phase of quetiapine (300mg/d or 600mg/d) or placebo. Patients on paroxetine received 300mg/d of quetiapine (continuation phase results not included here and to be presented separately).

**Results:** LSM MADRS score change at 8 weeks was -16.19 (quetiapine 300mg/d), -16.31 (quetiapine 600mg/d), -13.76 (paroxetine), and -12.60 (placebo;  $P < 0.001$  for both quetiapine doses,  $P = 0.313$  for paroxetine, versus placebo; LOCF ANCOVA). Quetiapine (both doses)-treated patients showed significantly greater improvements ( $P \leq 0.05$ ) in MADRS response rate, HAM-D, CGI-BP-S, CGI-BP-Change, HAM-A, and MADRS item 10 (suicidal thoughts) at Week 8 versus placebo; MADRS remission rates improved with quetiapine 600mg/d versus placebo ( $P = 0.012$ ). Paroxetine improved HAM-A scores versus placebo ( $P = 0.033$ ).

Most common adverse events considered drug-related included dry mouth, somnolence, sedation, and dizziness with quetiapine (both doses); dry mouth, sedation, headache, insomnia, and nausea with paroxetine.

**Conclusions:** Quetiapine (300mg/d or 600mg/d) was more effective than placebo for the treatment of acute depressive episodes in bipolar I and II disorder. Quetiapine treatment was generally well tolerated.

Supported by funding from AstraZeneca Pharmaceuticals LP.

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## Poster Session II: Cognitive Enhancing Drugs

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### P0162

Cognitive effects of acute Modafinil treatment in patients with sleep apnea

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