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ADAA: Nefazodone No More Effective than Placebo for Treatment of Social Phobia

By Thomas S. May

TORONTO, ON-- March 31, 2003 -- Results of a randomized, placebo-controlled study indicate that the serotonergic agent nefazodone is no more effective than placebo in the treatment of generalized social phobia.

Michael Van Ameringen, MD, of McMaster University in Hamilton, ON, Canada, presented these findings here March 29th at the 23rd Annual Conference of the Anxiety Disorders Association of America.

A number of serotonergic agents -- such as paroxetine, sertraline, and venlafaxine -- are approved for use in Canada and the United States for treatment of social phobia, Dr. Van Ameringen said. "However, the response rate to any of these agents is at best 50 to 60%," he said. "Moreover, a lot of the patients can't tolerate the side effects of these medications," he added.

Therefore, Dr. Van Ameringen and colleagues conducted a study to evaluate the efficacy, safety, and tolerability of nefazodone in patients with moderate to severe generalized social phobia (age 18-65 years) at 4 sites in Canada. They randomized 104 patients in a 1:1 ratio to receive 14 weeks of either nefazodone at a flexible dose of 300-600 mg/day or placebo.

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Primary outcome measures were the Clinical Global Impression Scale - Global Improvement Item (CGI-I) and the Liebowitz Social Anxiety Scale (LSAS). Secondary measures included the Social Phobia Inventory, Social Phobia Scale, Beck Depression Scale, and the Beck Anxiety Scale.

The primary efficacy measures were defined as the number of responders with CGI improvement scores of 1 or 2 ("much improved or "very much improved"). Measures were taken on weeks 3, 5, 7, and 14.

The study was completed by 69% of patients in the nefazodone group and 83% of the placebo group. The researchers obtained efficacy data for 102 patients.

Based on CGI scores, 31% of patients responded to nefazodone versus 23% to placebo. There was no statistical difference between the groups regarding the CGI or LSAS scores.

Not only did the researchers find that nefazodone was no better than placebo in treating generalized social phobia, but there were also more adverse events in the nefazodone group, and the dropout rate was higher.

"These findings are somewhat surprising, because some serotonergic antidepressants have been quite effective," Dr. Ameringen said.

He noted, however, that a couple of other studies of serotonergic agents, such as paroxetine and fluoxetine, failed to find a positive effect in social phobia.

"Our nefazodone study is negative as well, suggesting that not all of these drugs are the same," Dr. Ameringen concluded.

Bristol-Myers Squibb Canada Inc provided funding for this study.

[Study title: *Not All Serotonergic Agents Are Created Equal In Social Phobia. Nefazodone: A Placebo Controlled Trial. Abstract 327R*]



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