

SOUTHWESTERN NEWS

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85 PERCENT OF DEPRESSED PATIENTS IMPROVE WHEN TREATED WITH BOTH MEDICATION AND PSYCHOTHERAPY, STUDY FINDS

DALLAS – May 18, 2000 – In a national study of 681 chronically depressed patients, psychotherapy combined with the antidepressant Serzone improved mood in 85 percent of patients after only three months of treatment. A national research team, which included UT Southwestern Medical Center at Dallas researchers, reported their findings in today's *New England Journal of Medicine*.

Dr. John Rush, vice chairman for research in psychiatry, and Dr. Madhukar Trivedi, associate professor of psychiatry and principal investigator at the Dallas site, concluded that this combination therapy was overwhelmingly more effective than either medication or psychotherapy alone for treating chronic depression. Few studies have specifically addressed patients with chronic depression, and none have specifically studied psychotherapy for this group.

Trivedi said the 85 percent response rate is the highest for a three-month period for any peer-reviewed depression study. It is the largest study ever undertaken evaluating the three methods for treating chronic depression.

The research took place at a dozen outpatient psychiatric clinics and academic medical centers around the country. Patients either were treated with Serzone (nefazodone hydrochloride) twice a day, had 16 to 20 sessions of a particular type of psychotherapy (Cognitive Behavioral Analysis System of Psychotherapy, or CBASP, in which patients are taught to focus on the consequences of their behavior and to use a problem-solving approach for interpersonal difficulties) or a treatment package combining the two.

The patients in the study had each been depressed continuously for at least two years; most had experienced chronic depression for an average of 20 years. Over the 12-week study period, 55 percent of the Serzone-only group reported a positive response, and 52 percent of the CBASP-only group experienced a treatment response, whereas 85 percent of those who took

(MORE)

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both Serzone and underwent CBASP had a positive response to treatment.

Serzone is traditionally prescribed for the acute treatment of depression, as well as prevention of relapse in patients treated for depression. Those who took the drug, either alone or in combination with CBASP, reported improvement in mood much sooner than those in psychotherapy only. Patients taking Serzone did not experience the side effects of weight gain or sexual dysfunction typical of most antidepressants and reported improvement in insomnia, which is common among chronically depressed patients.

"These findings on the dual-treatment approach for the treatment of chronic depression are incredibly exciting," Trivedi said. "The large differences in response rates after only three months of treatment is truly astonishing. This approach has proven the kind of treatment we should be using with our chronically depressed patients."

The 12-week results represent the first phase of an ongoing 80-week study, which includes a 16-week trial for patients who responded positively to Serzone or the combination treatment and a 52-week maintenance phase to evaluate Serzone vs. a placebo.

Last May, preliminary findings of the Serzone Chronic Depression Study were announced at a press conference at the annual meeting of the American Psychiatric Association in Washington, D.C.

With 14 million Americans suffering from chronic depression, Trivedi hopes that insurance companies are taking note. "We expect that our findings will help with our battles about paying for the most effective treatments for depression," he said. Depression costs the U.S. economy \$53 billion each year.

Dr. Martin Keller, chairman of psychiatry and human behavior at Brown University, is the study coordinator. Bristol-Myers Squibb Co., manufacturer of Serzone, funded the study.

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