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Antidepressant-suicide link in youths absent in new analysis

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In 2004, concerns about antidepressant drugs increasing suicidal thoughts and behaviors in young patients prompted the FDA to issue a rare "black box warning." Now, a new analysis of clinical trial data finds that treatment with the antidepressant fluoxetine did not increase — or decrease — suicidality in children compared to placebo treatment.

An analysis built on data from 41 trials and more than 9,000 patients also found that two different popular antidepressant drugs were effective at reducing suicidal behavior and depressive symptoms in adult and geriatric patients. The findings are published online Feb. 6 in the journal *Archives of General Psychiatry*.

The failure to replicate the link between antidepressants and suicide should reassure doctors about prescribing these drugs to depressed patients, said first author Robert Gibbons, PhD, professor of medicine, health studies, and psychiatry at the University of Chicago Medicine.

"The key finding here, when we re-analyze all the patient-level longitudinal records in these studies, is that antidepressants neither increase nor decrease suicidal thoughts or behavior in children," Gibbons said.

The FDA decision on the black box warning was based on retrospective data from 25 clinical trials of newer antidepressant medications, including the serotonin reuptake inhibitor drug fluoxetine, marketed as Prozac or Sarafem. A meta-analysis combining adverse event data

(primarily based on self reports of suicidal thoughts) from the trials revealed a small, but significant, increase in suicidal thoughts and behavior in children and young adults up to the age of 25.

For the new analysis, Gibbons and colleagues from the University of Illinois at Chicago, the University of Miami and Columbia University obtained individual-level, longitudinal clinical trial data — some of it unpublished — from pharmaceutical producers and a large National Institute of Mental Health collaborative study of fluoxetine and venlafaxine. The data included weekly screening of each trial subject for depression and suicidal thoughts, allowing researchers to compare the effect of drug or placebo over time on these measures.

In the analysis of the adult and geriatric trials testing fluoxetine or venlafaxine, both antidepressants were found effective in reducing suicide risk and depression symptoms. These two effects were also found to be statistically associated, suggesting that the drugs reduced suicidality by alleviating depression. Therefore, Gibbons said, effective treatment of major depressive disorder is important for a patient's safety.

"Basically, the results say that the mechanism by which the antidepressants affect suicide rates is by decreasing depression," Gibbons said. "It follows that if a treatment is not working for an individual, the risk for suicidal behavior and perhaps worse remains high."

To analyze the effects of antidepressants in children, the researchers used four trials of fluoxetine, which until recently was the only antidepressant approved for pediatric use. Once again, a reduction in depressive symptoms was observed in the drug-treated population compared to placebo. However, no significant change in suicide risk was detected between the two patient groups.

"I think that this paper supports the general idea that the effects of antidepressants in kids and adults are not really the same, since we don't see anything but beneficial effects of antidepressants in adults and geriatrics," Gibbons said. "In kids, we don't see a harmful effect, but we do see a disassociation between the beneficial effects on depression and the potential beneficial effect on suicide."

"This raises continued questions about what's going on in children," he continued. "Maybe children think about suicide in part because of depression, but also maybe due to other reasons not related to depression that are not affected by antidepressants."

Gibbons, who sat on the Food and Drug Administration panel that considered placing the black box warning on antidepressants, said he hoped the new results would reassure clinicians about the safety of the drugs. Previous research by his group found that the addition of the warning significantly reduced antidepressant prescriptions to both children and adults and correlated with a spike in suicide rates.

"I hope that the warnings will not prevent depressed children and adults from getting treatment for depression," Gibbons said. "The greatest cause of suicide is untreated or undiagnosed depression. It's very important that this condition be recognized and appropriately treated and not discarded because doctors are afraid to be sued."

More information: The paper, "Suicidal Thoughts and Behavior with Antidepressant Treatment," will be published online February 6th by *Archives of General Psychiatry.*

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