

ADHD Drugs: Sudden Death Risk Higher?

Study Suggests Link Between Some ADHD Drugs and Sudden Cardiac Death in Children

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June 15, 2009 -- A new study suggests that children and [teens](#) who take stimulants like [Ritalin](#) for [ADHD](#) have an increased risk for sudden cardiac death, but the FDA says the study has major limitations and should not change the way the [drugs](#) are used.

There have long been concerns that the stimulants used to treat ADHD may increase the risk for sudden death in children with undiagnosed heart conditions. The new research finds corroborating evidence for concern, although all agree that the risk of sudden cardiac death is very small.

ADHD Stimulants and Sudden Cardiac Death

Researchers collected data on stimulant use among 564 children and teenagers who died unexpectedly of unknown causes and an equal number who died as passengers in auto accidents. Many of the unexplained deaths were later attributed to previously undiagnosed cardiac arrhythmias.

They concluded that the odds of using stimulant medication were six to seven times greater among the children who died suddenly of unexplained causes than among those who died in car crashes. Ten children who died of unknown causes (just under 2%) took stimulants, compared to two children (0.4%) who died in auto accidents.

The study does not prove that ADHD drugs cause cardiac deaths. But lead researcher Madelyn S. Gould, PhD, tells WebMD that the results highlight the importance of carefully screening children and teens for heart conditions when the medications are prescribed.

The research was published today online and will appear in *The American Journal of Psychiatry*. “These are very rare events, and parents should not be overly concerned,” she says. “This shouldn’t stop anyone from using medications that can help children. But the clinicians who prescribe these drugs must be vigilant about screening and monitoring their patients.”

FDA: Study Doesn’t Prove Link

The FDA and the National Institute of Mental Health funded the study, but FDA officials expressed reservations about the findings in a written statement and news briefing held today.

“Given the limitations of this study’s methodology, the FDA is unable to conclude that these data affect the overall risk-and-benefit profile of stimulant medications used to treat [ADHD in children](#).” The biggest limitation, FDA officials said, is that information on stimulant use was collected years and in some cases a decade or more after the children died. They expressed concern that recalling their children's stimulant use many years later might be greater for parents and physicians of children who died suddenly of unexplained causes.

Robert Temple, MD, of the FDA, said an ongoing study of cardiac outcomes among children taking stimulants for ADHD should provide additional information about risk. Results from this study, also funded by the FDA and the Agency for Healthcare Research and Quality (AHRQ), should be published in a few months, he said.

ADHD Drugs Have Warnings

It is estimated that more than 2.5 million children and teens in the United States take stimulants to control their ADHD. Drugs like Ritalin, Adderall, [Dexedrine](#), and Concerta are known to increase heart rates and raise [blood pressure](#), but the risk has not been considered significant in otherwise healthy children.

The FDA requires that these drugs include labeling warning of the risk of sudden cardiac death in patients with heart problems, but the incidence of cardiac events among children and teens taking the drugs for ADHD is not known.

In March of 2006, an FDA panel reported that between 1992 and 2005, 11 sudden cardiac deaths occurred in children taking Ritalin and Concerta, which both contain the stimulant [methylphenidate](#), and 13 sudden cardiac deaths occurred among children taking the [amphetamine](#)-containing stimulants Adderall and Dexedrine. Three sudden cardiac deaths were also reported among children taking the ADHD drug [Strattera](#), which is not a stimulant.

Late last year, a special panel of the American Heart Association recommended screening all children and teens taking ADHD drugs for hidden heart problems. The panel also called for electrocardiogram (ECG) screening of all patients being placed on the stimulants for the first time.

Editorial: ‘Drugs Aren’t Innocuous’

In an editorial published with the study, Benedetto Vitiello, MD, and Kenneth Towbin, MD, of the National Institute of Mental Health, write that this report “should underscore that stimulants are not innocuous and that their therapeutic use requires careful diagnostic assessment, diligent safety screening, and ongoing monitoring.”

Ritalin, Concerta, and other ADHD drugs are increasingly being used recreationally, usually in an effort to boost academic or job performance. Vitiello tells WebMD that recreational users mistakenly think of these drugs as safe. “These drugs are being widely misused, and people need to know that they are not benign,” he says.

A spokeswoman for McNeil Pediatrics, which makes Concerta, told WebMD that the company “welcomes any data that adds to the body of knowledge in this therapeutic area.”

Calls to Shire Pharmaceuticals, which manufactures Adderall, and Novartis Pharmaceuticals, which markets Ritalin LA, were not returned in time for publication.

Gould, M.S. *The American Journal of Psychiatry*, published online June 15, 2009. Madelyn S. Gould, PhD, MPH, professor of clinical epidemiology and psychiatry, Columbia University, New York; research scientist, New York State Psychiatric Institute. Benedetto Vitiello, MD, Division of Services and Intervention Research and Mood and Anxiety Disorders Program, National Institute of Mental Health, Bethesda, Md. Victoria L. Vetter, MD, chief of cardiology, Children’s Hospital of Philadelphia.

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