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ADHD drugs linked to sudden death in kids

By Serena Gordon, *HealthDay Reporter*

As many as 2.5 million children in the United States take ADHD stimulant medications, such as amphetamine, dextroamphetamine (Adderall), methamphetamine or methylphenidate (Ritalin), according to an editorial in the same issue. © iStockphoto.com

MONDAY, June 15 (HealthDay News) -- Stimulant medications commonly prescribed to treat attention-deficit hyperactivity disorder (ADHD) are associated with an increased risk of sudden death, but those deaths are still rare, new research finds.

Children and teens taking ADHD stimulant medications were seven times more likely to die suddenly than their peers, the study found.

"What we found -- to our surprise -- is that even if you take out confounding factors, the association between stimulant use and sudden death was still significant," said study author Madelyn Gould, a professor of clinical epidemiology in psychiatry at Columbia University/New York State Psychiatric Institute in New York City. "I'm confident the association is real and significant, but it's very rare. I don't want our findings to change prescribing patterns or for a parent to change their willingness to use stimulant medications if they're called for, but physicians should monitor patients with any new medication you give a young person."

Results of the study were published in the June 15 online edition of the *American Journal of Psychiatry*.

As many as 2.5 million children in the United States take ADHD stimulant medications, such as amphetamine, dextroamphetamine (Adderall), methamphetamine or methylphenidate (Ritalin), according to an editorial in the same issue.

In the early 1990s, several reports of sudden, unexplained death in children taking these medications began to raise concerns. But the rarity of such deaths made them difficult to study. In 2006, the U.S. Food and Drug Administration requested that the prescribing information on these medications warn physicians against ordering the drugs for children with any known cardiac abnormalities. Current prescribing information also suggests that physicians request a thorough family history of heart problems and sudden deaths and perform a physical exam before starting youngsters on these medications.

Gould said the FDA approached her and her colleagues to try to assess the true prevalence of this problem.

The researchers sifted through mortality data from 1985 through 1996, and found 564 cases of sudden death that occurred in children aged 7 to 19, and they compared them to 564 youths who had been killed as passengers in automobile accidents.

After ruling out factors such as a history of known cardiac problems; known causes of death, such as asthma or an accidental death; and other conditions, such as sickle cell anemia or cerebral palsy, Gould and her colleagues found only 10 sudden, unexplained deaths in children taking stimulant medications.

When they compared those 10 youths to age-matched controls who had died in car crashes, they found that the odds of sudden death were 7.4 times higher for children taking stimulant

medications.

"Stimulants do increase blood pressure, and there have been reports of them changing heart rates," noted Gould.

"This report is quite helpful," said one of the authors of the accompanying editorial, Dr. Benedetto Vitiello, a psychiatrist and chief of the child and adolescent treatment intervention branch at the U.S. National Institute of Mental Health. "It rings a bell for everyone to be more attentive and less cavalier about the use of these drugs."

Many teens and even some adults take them for non-approved uses, such as improving focus and enhancing performance at work or at school.

"We need to keep in mind that even though these drugs are commonly used, they still have the potential for adverse events. We shouldn't approach them lightly," said Vitiello.

Dr. Diego Chaves-Gnecco, a developmental-behavioral pediatrician at Children's Hospital of Pittsburgh, agreed with Vitiello.

"No medication is free of risk or side effects. Any time we prescribe any medication, we have to balance its benefits and risks," he said.

In the case of stimulant medications, he said, physicians should follow recently developed guidelines and take a thorough personal and family history before prescribing them. If any concerns arise, the child should be referred for an EKG (a heart rate test) or an evaluation by a pediatric cardiologist before medication is prescribed.

If your child has been on stimulants for awhile, there's probably no need for concern, Gould said. Parents should not abruptly stop their child's medications, the three experts agreed. If you are worried, call the prescribing doctor and discuss the potential risks and benefits of the medications, because often the benefits will outweigh the risks.

"The most important point is to make sure that everyone is well-educated and that a conscientious screening has been done," said Chaves-Gnecco.

The FDA was quick to react to the publication of the study, saying that it was not definitive and cannot be used to change current practice. The agency recommended that doctors continue to follow the current safety warnings attached to these drugs.

"These drugs do pose a risk to children with underlying heart disease," Dr. Robert Temple, director of the FDA's Office of Drug Evaluation I, said during a Monday press conference. "So there is labeling that says you should be very careful and probably not use them in those people."

The question is do these drugs cause a problem to people without underlying heart disease, Temple said.

The problem with the new study is that it's not known for sure whether the people in the study were taking an amphetamine, Temple said.

To try to get definitive data on the risk of these drugs, the FDA said it's undertaking two studies that will look at the outcomes of people taking these medications.

More information

Learn more about stimulant medications for ADHD from the Nemours Foundation's KidsHealth Web site.

SOURCES: Madelyn S. Gould, M.P.H., professor, clinical epidemiology in psychiatry, Columbia University/New York State Psychiatric Institute, New York City; Diego Chaves-Gnecco, M.D., developmental-behavioral pediatrician, Children's Hospital of Pittsburgh, Penn.; Benedetto Vitiello, M.D., psychiatrist and chief, child and adolescent treatment intervention branch, National Institute of Mental Health, Bethesda, Md.; *American Journal of Psychiatry* online, June 15, 2009; June 15, 2009 teleconference with Gerald Dal Pan, M.D., director, Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, and Robert Temple, M.D., director, Office of Drug Evaluation I, CDER, FDA