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ARTICLE

Hallucinations and Other Psychotic Symptoms Associated With the Use of Attention-Deficit/Hyperactivity Disorder Drugs in Children

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What's Known on This Subject

Hallucinations as an adverse effect of stimulant therapy have been described since at least 1967. Stimulant overdose can cause hallucinations and other psychotic symptoms. Psychiatric adverse events reported during clinical trials with atomoxetine included agitation, mania, and hypomania.

What This Study Adds

We describe a comprehensive review of clinical trial data, as well as postmarketing spontaneous reports, examining the occurrence of hallucinations and other psychotic symptoms during drug therapy for ADHD.

ABSTRACT

OBJECTIVES. To gain a better understanding of the capacity of psychostimulant medications to induce adverse psychiatric reactions and determine the frequency of such reactions, we analyzed postmarketing surveillance data and clinical trial data for drugs, either approved or under development, for the treatment of attention-deficit/hyperactivity disorder.

METHODS. The US Food and Drug Administration requested manufacturers of drugs approved for attention-deficit/hyperactivity disorder or with active clinical development programs for that indication to search their electronic clinical trial databases for cases of psychosis or mania using prespecified search terms. The manufacturers supplied descriptions of clinical trials, numbers of patients exposed to study drug, and duration of exposure to permit calculations of incidence rates. Independently, cases of psychosis or mania in children and adults for drugs used to treat attention-deficit/hyperactivity disorder from the Food and Drug Administration Adverse Event Reporting System safety database were analyzed. Manufacturers were asked to conduct similar analyses of their postmarketing surveillance databases.

RESULTS. We analyzed data from 49 randomized, controlled clinical trials in the pediatric development programs for these products. A total of 11 psychosis/mania adverse events occurred during 743 person-years of double-blind treatment with these drugs, and no comparable adverse events occurred in a total of 420 person-years of placebo exposure in the same trials. The rate per 100 person-years in the pooled active drug group was 1.48. The analysis of spontaneous postmarketing reports yielded >800 reports of adverse events related to psychosis or mania. In ~90% of the cases, there was no reported history of a similar psychiatric condition. Hallucinations involving visual and/or tactile sensations of insects, snakes, or worms were common in cases in children.

CONCLUSIONS. Patients and physicians should be aware that psychosis or mania arising during drug treatment of attention-deficit/hyperactivity disorder may represent adverse drug reactions. *Pediatrics* 2009;123:611–616

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Key Words
ADHD, adverse drug reactions, drug safety, psychiatric issues in primary care

Abbreviations
ADHD—attention-deficit/hyperactivity disorder
CI—confidence interval
FDA—Food and Drug Administration
PAC—Pediatric Advisory Committee
AERS—Adverse Event Reporting System

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ATTENTION-DEFICIT/HYPERACTIVITY DISORDER (ADHD) has become an increasingly common diagnosis in US school-aged children, many of whom are treated with medication. According to a survey conducted in 2003 by the US Centers for Disease Control and Prevention, ~7.8% of US children aged 4 to 17 years (4 418 000 children [95% confidence interval (CI): 4 234 000–4 602 000 children]) had ever received a diagnosis of ADHD, and an estimated 4.3% of US children in this same age group were taking medication for ADHD. Rates of medication treatment for ADHD varied by age and gender and ranged from 0.3% to 9.3%.[1] Accordingly, the public health burden from an adverse reaction to an ADHD medication can be significant, and it is important to be able to characterize the adverse reaction profile of these medications.

The present effort to characterize psychiatric adverse events among patients treated with drugs for ADHD arose from a public discussion at the June 30, 2005, meeting of the US Food and Drug Administration (FDA) Pediatric Advisory Committee (PAC).[2] The PAC members raised concerns about potential drug-related psychiatric adverse effects. In response to this concern, the FDA Office of Surveillance and Epidemiology conducted a comprehensive review of psychiatric adverse events reported during treatment with current and pending ADHD drugs for which clinical trial data had been submitted to the FDA. The results of this analysis were presented to the public at a PAC meeting on March 22, 2006,[3] and are described here to provide a reference for clinicians who are interested in the basis for the recent FDA notice[4] about increased risk of psychosis or mania symptoms in children being treated with currently available medications for ADHD. The pooled clinical data presented here, submitted by the drug manufacturers in response to the FDA request, as well as the analysis of postmarketing spontaneous case reports, focus on psychosis or mania-type psychiatric adverse events.

METHODS

Clinical Trials

The FDA requested manufacturers of marketed drugs either approved for ADHD or with active clinical development programs for that indication to perform a prespecified string search of their electronic clinical trial databases using standard dictionary-coded adverse-event terms related to psychosis or mania, which included hallucination (any type, eg, visual, auditory, tactile, mixed, etc), delusion (any type, eg, somatic, persecutory, grandeur, and reference), schizophrenia (any type), psychotic disorder, transient psychosis, acute psychosis, paranoia, childhood psychosis, schizophreniform disorder, schizoaffective disorder, catatonia, mania, and hypomania.

Drugs included in the FDA request were Adderall XR (mixed salts of a single entity amphetamine product) extended-release capsules (Shire US Inc, Wayne, PA), Focalin (dexmethylphenidate hydrochloride) tablets (Novartis Pharmaceuticals Corporation, East Hanover, NJ), Focalin XR (dexmethylphenidate hydrochloride) extended-release capsules (Novartis Pharmaceuticals Corporation), Concerta (methylphenidate hydrochloride) extended-release tablets (ALZA Corporation, Mountain View, CA), Metadate CD (methylphenidate hydrochloride) extended-release capsules (Celltech Pharmaceuticals, Inc, Rochester, NY), Ritalin LA (long-acting, methylphenidate hydrochloride) extended-release capsules (Novartis Pharmaceuticals Corporation), Strattera (atomoxetine hydrochloride) capsules (Eli Lilly and Company, Indianapolis, IN), Daytrana Methylphenidate transdermal system (Shire US Inc), and Provigil (modafinil) tablets (Cephalon, Inc, Frazer, PA) (the ADHD indication is not approved for modafinil, which is associated with serious dermatologic reactions[5]). Although these drugs have somewhat diverse pharmacology and mechanisms of action,[6] for this analysis we decided to group them empirically by their approved or proposed use in the treatment of ADHD, rather than by their pharmacology.

Drug manufacturers were requested to report events meeting the selection criteria that occurred during pediatric randomized, controlled clinical trials or within 48 hours of the end of treatment. In addition, duration of treatment was provided in person-days. Patients with >1 event were counted only once. Data from open-label trials and adult ADHD trials were also requested but were not used for the analysis presented herein.

We calculated the rate of the events of interest per 100 person-years with the 95% Poisson exact CI. We did not calculate risk ratios because of the absence of events in any of the placebo groups. Data were analyzed by using 2 statistical software packages: JMP 6.0 (SAS Institute, Inc, Cary, NC) and Stata/SE 8.2 for Windows (Stata Corp, College Station, TX).

Postmarketing Spontaneous Reports

In a separate analysis, we queried the FDA Adverse Event Reporting System (AERS) safety database for adverse-event terms related to psychosis or mania associated with drugs used for ADHD. Prespecified search terms[7] were used to identify reports received from January 1, 2000, through June 30, 2005. This search included both pediatric and adult case reports. Each case report was individually assessed by a team of safety evaluators at the FDA to exclude duplicates, as well as reports considered to be of poor quality, and to assess the pertinent clinical information in each case using a predefined data retrieval form. Simultaneously, each drug manufacturer was asked to provide similar psychiatric adverse-event data sets retrieved from their own safety database. Postmarketing spontaneous reports were evaluated by the FDA team using criteria adapted from Naranjo et al[8] to assess the probability of adverse drug reactions and to describe characteristics or risk factors observed in each case. Evaluation criteria included assessment of temporal association, dechallenge and rechallenge information, presence of alternative explanations or risk factors, and whether the case was confirmed by a medical professional.

RESULTS

Clinical Trials

The requests yielded data on 49 randomized, controlled clinical trials in the pediatric development programs for these products. Table 1 presents an overview of the clinical trials and the psychiatric adverse events. Table 2 displays the results obtained by the crude pooling of the pediatric double-blind trial data in primary drug and placebo groups. Psychosis/mania events occurred during double-blind treatment with every compound (11 events total) except Adderall XR (extended release), although there were psychosis/mania events with open-label Adderall XR treatment). The rate per 100 person-years in the pooled active drug group was 1.48 (95% Poisson exact CI: 0.74–2.65 per 100 person-years). In contrast, among all of the pediatric ADHD patients in placebo treatment groups, totaling 420 person-years of

TABLE 1 Summary of Pediatric ADHD Clinical Trials and Psychiatric Adverse Events

Drug	No. of Trials	Treatment	Exposure in Trials, Person-Years	Psychosis/Mania Events, *n*
Ritalin LA	3	Placebo	8.6	0
		Drug	9.9	0
Modafinil	5	Placebo	32.5	0
		Drug	75.1	2
MTS	8	Placebo	23.8	0
		Drug	30.3	4
Metadate CD	4	Placebo	19.4	0
		Drug	19.1	0
Dextromethylphenidate	7	Placebo	48.5	0
		Drug	49.7	1
Concerta	4	Placebo	10.2	0
		Drug	12.5	0
Adderall XR	4	Placebo	21.0	0
		Drug	59.0	0
Atomoxetine	14	Placebo	256.0	0
		Drug	487.5	4

MTS indicates methylphenidate transdermal system.

placebo exposure, there were no psychosis/mania adverse events.

Postmarketing Spontaneous Case Reports

Overall, findings from the review of spontaneous postmarketing case reports were similar whether based on the spontaneous case reports retrieved by the FDA or based on the cases identified in searches done by each of the drug manufacturers. A complete report describing the totality of the data is available on the FDA Web site.[7] Table 3 summarizes some characteristics of the postmarketing spontaneous case reports from the manufacturers of drugs currently approved and marketed for ADHD.

In total, there were 865 unique postmarketing case reports describing signs and/or symptoms of psychosis or mania contained in analyses from the drug manufacturers. The majority of these were pediatric cases, with nearly half of the cases overall reported in children age ≤10 years. As shown in Table 3, many of the cases (30%–78%, depending on drug) were confirmed by a health professional, and all stated positive temporal association with ADHD drug administration. The percentage of cases reporting positive dechallenge (resolution of symptoms after drug is stopped) ranged from 25% to 59%, depending on the drug; however, information about resolution of symptoms was not provided in many reports. Cases with positive rechallenge (ie, recurrence of symptoms when the drug is reintroduced after having been stopped because of a suspected drug-related adverse event) are often considered to be indicative of a causal association and were reported for each of the drugs included in this analysis.

No risk factors were identified that could account for the majority of reports of psychosis or mania-related events. For instance, drug abuse was reported in <3% of overall cases from the FDA AERS analysis. In the vast majority of cases (~90%), there was no previous history of a similar psychiatric condition reported. In clinical narratives submitted by manufacturers and also in published case reports,[9,10] a common theme in young children with hallucinations involved descriptions of visual and/or tactile sensations of insects, snakes, or worms. When the drug was discontinued, the psychosis/mania-type symptoms often resolved.

Representative clinical narratives that were presented at the PAC meeting in March 2006 included a published case report[10] of a 12-year-old boy with cerebral palsy and low normal intelligence who was treated for ADHD with 0.3 mg/kg (10 mg) of methylphenidate daily, with good clinical response. However, he developed visual hallucinations of roaches surrounding him, beginning 2 hours after his dose of methylphenidate and lasting for 2 hours. The hallucinations ceased when methylphenidate was discontinued but returned when the patient was rechallenged with the drug. Subsequently, the patient experienced no additional hallucinations in 3 years of follow-up off methylphenidate therapy.

A spontaneous report from the manufacturer of Adderall XR (mixed salts of a single-entity amphetamine product) extended-release capsules described a 7-year-old boy who experienced visual hallucinations and paranoid behaviors while taking 20 mg per day of Adderall XR for ADHD. The child exhibited "irrational behaviors and bizarre behaviors." There were no concomitant medications, concurrent medical conditions, or pertinent past medical history reported. Both visual hallucinations and paranoid behavior resolved with discontinuation of the medication.

A spontaneous report from the manufacturer of Strattera (atomoxetine) described a 7-year-old girl who received 18 mg daily of atomoxetine for the treatment of ADHD. Within hours of taking the first dose, the patient started talking nonstop and stated that she was happy. The next morning the child was still elated. Two hours after taking her second dose of atomoxetine, the patient started running very fast, stopped suddenly, and fell to the ground. The patient said she had "run into a wall" (there was no wall there). The reporting physician considered that the child was hallucinating. Atomoxetine

TABLE 2 Aggregated Adverse-Event Data From Pediatric Double-Blind ADHD Trials

Treatment	*n*	Person-Years	Mean Duration of Treatment, d	Psychosis/Mania Events, *n*	Percentage of Patients With Events	Rate of Psychosis/Mania Events per 100 Person-Years, Rate (95% CI)
Placebo	3990	420	39	0	0.00	0 (0)
Active drugs[a]	5717	743	51	11	0.19	1.48 (0.74–2.65)

[a] Drugs include Adderall XR, atomoxetine, modafinil, oral methylphenidates, and methylphenidate transdermal system.

TABLE 3 **Postmarketing Spontaneous Case Reports From Manufacturers of Currently Marketed ADHD Drugs: Signs and/or Symptoms of Psychosis or Mania, January 1, 2000, Through June 30, 2005 (Includes Pediatric and Adult Cases)**

Drug	No. (%) of Subjects With Selected Criteria Present					
	Temporal Association	Positive Dechallenge	Positive Rechallenge	No Concomitant Medications Reported	No Previous History of Same Event	Medical Professional Confirmation
Adderall	84 (100)	28 (33)	2 (2.0)	16 (19)	82 (98)	25 (30)
Adderall XR	92 (100)	34 (37)	3 (3.0)	20 (22)	89 (97)	46 (50)
Concerta	160 (100)	70 (44)	1 (0.6)	110 (69)	150 (94)	125 (78)
Metadate	39 (100)	23 (59)	1 (3.0)	21 (54)	36 (92)	20 (51)
Ritalin	130 (100)	32 (25)	1 (1.0)	90 (69)	116 (89)	97 (75)
Strattera	360 (100)	95 (26)	1 (0.3)	77 (21)	323 (90)	250 (69)

was discontinued. No additional information was provided.

DISCUSSION

Overall, data from controlled clinical trials and postmarketing surveillance show that some patients, including some with no identifiable risk factors, can develop drug-related signs or symptoms of psychosis or mania, such as hallucinations, at usual doses of frequently used ADHD drugs. Based on the pooled placebo experience in pediatric ADHD clinical trials, such signs and symptoms were not observed in untreated children with ADHD.

The review of spontaneous case reports of patients treated for ADHD with amphetamine/dextroamphetamine, atomoxetine, or methylphenidate indicated a likely causal association between each of these drugs and treatment-emergent onset of signs and symptoms of psychosis or mania, notably hallucinations, in some patients. Case reports included strong temporal association, many with positive dechallenge, some with positive rechallenge, and many reports with few confounders, such as pre-existing history of similar condition, concomitant medications, or drug abuse. Confirmation by a health professional was provided in 30% to 85% of the case reports, depending on the drug and the manufacturer.

The numbers of cases of psychosis or mania in pediatric clinical trials were small. However, we noted the complete absence of such events with placebo treatment. For 4028 pediatric ADHD patients in these trials, there were no such events in 420 person-years of aggregated placebo treatment. Similarly, there were no psychosis or mania events in these trials among 578 adult ADHD patients receiving placebo for a total exposure time of 111.5 person-years in the adult age group (data not shown). Psychosis/mania events occurred during double-blind treatment with every compound except Adderall XR (extended release, although there were psychosis/mania events with open-label Adderall XR treatment).

As noted, rates of adverse drug effects in clinical trials, where patients are carefully selected for a high likelihood of treatment success (ie, known to respond to stimulants or who had no history of intolerance to stimulants), may greatly underestimate the incidence of adverse effects in the general population. Very little information is available about the incidence of adverse effects in the general population. An outpatient clinic in Canada reported that, over a 5-year period between 1989 and 1995, of 98 children who were treated for ADHD with stimulant drugs, 6 children developed psychotic symptoms during treatment.[11] In another case series, Henderson and Hartman[12] reported that, of 153 pediatric patients treated with atomoxetine at their outpatient clinics, 10 developed frank mania. However, much lower incidence estimates derived from the randomized clinical trial experience are the basis for the conclusion in a recent clinical review that "toxicosis will occur in approximately 0.25% of children treated with stimulants, or about 1 in 400—a proportion suggesting an infrequent but not rare effect of therapeutic dosing."[13]

This analysis of clinical trial data examining adverse effects of ADHD drug therapy builds on previous observations by adding information on estimated short-term incidence and the absence of similar drug-induced adverse effects in placebo groups. Previous studies have implicated dopaminergic mechanisms in the pathophysiology of psychosis and mania.[14] The finding of hallucinations as an adverse effect of stimulants has been repeatedly reported since at least 1967.[15–18] Moreover, the clinical manifestations of stimulant overdose toxicity are consistent with the adverse effects currently under discussion.[19]

Overall, nearly half of the postmarketing spontaneous reports involved children ≤10 years of age. The occurrence of psychosis or mania-type symptoms in young children may be particularly traumatic and undesirable, both to the child and the parents. It may help mitigate parental/patient anxiety if the prescribing physician discussed before starting treatment that the emergence of psychosis or mania-type symptoms during treatment may be because of an adverse reaction from the drugs themselves. Based on recommendations of the PAC in 2006, the FDA asked ADHD drug manufacturers to add new warnings for cardiovascular and psychiatric adverse effects to the US package inserts for each of these products. In addition, medication guides are now required, explaining the risks of ADHD drug treatments and advising patients and prescribers about possible adverse effects to watch for.[4]

The limitations of spontaneous postmarketing report data are well known and include underreporting of adverse drug reactions to AERS, a high frequency of reports with missing information, and difficulty obtaining follow-up information on reported cases. In addition, there are factors that limit the use of the clinical trial data. Some of these limitations apply whenever clinical trial data are aggregated for analysis. For one, there is the issue of whether adverse events are ascertained with the same level of sensitivity by different investigators and in different trials. This can present challenges when making comparisons between trials and between development programs. Second, there is the issue of whether cases could have been misclassified. The data presented herein were based on each manufacturer's adverse-event classifications, but the methods used to produce these classifications varied across manufacturers. Third, the statistical power of such safety analyses is always limited by the sample sizes of the trials considered.

In addition to general limitations that apply to all such safety analyses, there are additional limitations specific to these data. First, a large number of the controlled trials required subjects who were known to respond to stimulants or who had no history of intolerance to stimulants. This tends to limit the external generalizability of safety data collected from samples of such subjects, especially when the data obtained from the subjects show relatively infrequent adverse events. Second, the duration of exposure in many of the trials was not likely to have been sufficient for the determination of infrequent adverse events; for example, although >1000 pediatric subjects received double-blind treatment in 1 set of clinical trials, the average duration of exposure to double-blind treatment was only 23 days. It is relevant to note that, although the onset of psychiatric symptoms occurred within days or weeks of starting ADHD drug therapy in approximately two thirds of the spontaneous MedWatch report, which included time to onset information, symptom onset began after months or, in a few cases, after years of treatment in the remaining third. To a certain degree this issue can be (and was) mitigated by greater exposure time in open-label trials, but open-label data are of less inferential value than controlled data. The exception to this was the development program for atomoxetine, which included >500 person-years of double-blind atomoxetine pediatric exposure. Given all of the these limitations, however, it is important to note that most of these limitations might actually underestimate the magnitude of the safety signal and are not likely to identify a spurious one.

CONCLUSIONS

Patients and physicians should be aware of the possibility that psychiatric symptoms consistent with psychosis or mania, when they arise in the course of drug treatment of ADHD, may represent adverse drug reactions. In terms of future clinical trial designs, it should be borne in mind that short-duration trials and trials that exclude subjects who are naive to this class of drug have limitations for defining the safety profile of the drug. It bears emphasis that the clinical trial population for these studies was, in many cases, screened for a history of intolerance to stimulants, so rates of adverse reactions observed among these subjects may be an underestimate of the rates in a less select group of patients.

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